

No. 2024-1285

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors,

On Appeal from the United States International Trade Commission
in Investigation No. 337-TA-1276

**NON-CONFIDENTIAL REPLY IN SUPPORT OF APPELLANT APPLE
INC.'S EMERGENCY MOTION TO STAY ENFORCEMENT OF ITC'S
ORDERS PENDING REVIEW**

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January 15, 2024

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
ARGUMENT	3
I. LIKELIHOOD OF SUCCESS	3
A. Apple Will Likely Prevail On Domestic Industry	3
B. Apple Will Likely Prevail On Validity	6
C. Apple Will Likely Prevail On Laches	8
II. IRREPARABLE HARM.....	9
III. BALANCE OF EQUITIES	10
IV. PUBLIC INTEREST.....	11
CERTIFICATE OF INTEREST	i
ADDENDUM	
CERTIFICATE OF SERVICE	
CERTIFICATE OF COMPLIANCE	

Rule 25.1(e)(1)(B) Statement: The material omitted on page 4 contains information that complainants Masimo Corporation and Cercacor Laboratories, Inc. designated as Confidential Business Information under the Administrative Protective Order in effect in ITC Investigation No. 1276. The material omitted on pages 10 and 12 contains information that Appellant Apple Inc. designated as confidential regarding its proposed redesign for the infringing Apple Watches.

TABLE OF AUTHORITIES

CASES

	Page(s)
<i>Align Technology, Inc. v. International Trade Commission</i> , 771 F.3d 1317 (Fed. Cir. 2014)	8
<i>In re Epstein</i> , 32 F.3d 1559 (Fed. Cir. 1994)	6
<i>In re Lee</i> , 277 F.3d 1338 (Fed. Cir. 2002)	1
<i>In re Paulsen</i> , 30 F.3d 1475 (Fed. Cir. 1994)	7
<i>Metalcraft of Mayville Inc. v. The Toro Company</i> , 848 F.3d 1358 (Fed. Cir. 2017)	9
<i>Microsoft Corp v. DataTern, Inc.</i> , 755 F.3d 899 (Fed. Cir. 2014)	1
<i>Rasmusson v. SmithKline Beecham Corp.</i> , 413 F.3d 1318 (Fed Cir. 2005)	7
<i>Sonos, Inc. v. Google LLC</i> , 2023 WL 6542320 (N.D. Cal. Oct. 6, 2023)	8
<i>Trustees in Bankruptcy of North American Rubber Thread Co. v.</i> <i>United States</i> , 593 F.3d 1346 (Fed. Cir. 2010)	11

STATUTES

35 U.S.C. § 112	7
-----------------------	---

OTHER AUTHORITIES

Order Granting-In-Part and Denying-In- Part Apple’s Rule 50(a) Motion, <i>Apple Inc. v. Masimo Corp.</i> , No. 8-20-cv-00048-JVS (C.D. Cal. May 4, 2023) (ECF No. 1724)	2
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The Commission’s opposition relies heavily on new substantive arguments—including accusations of waiver—not in the stay decision below. This approach is procedurally improper under the *Chenery* principle that “review of an administrative decision must be made on the grounds relied on by the agency.” *In re Lee*, 277 F.3d 1338, 1345-1346 (Fed. Cir. 2002). Moreover, the new arguments are meritless and only serve to highlight the Commission’s lack of understanding of its own record.

Masimo, too, advances numerous new points, including in an improper 7,500-word declaration from its CEO. The declaration should be disregarded, as (1) it is a “fundamentally unfair” attempt to exceed the word limit, *Microsoft Corp v. DataTern, Inc.*, 755 F.3d 899, 910 (Fed. Cir. 2014), (2) it was never submitted to the Commission, contains many new alleged facts, and cites 32 exhibits outside the Commission record, and (3) Mr. Kiani plainly lacks personal knowledge for many statements.¹

Regardless, the declaration’s self-aggrandizing statements about the purported value of Masimo’s technology cannot be squared with Masimo’s repeated losses in the courts. This Court has affirmed the unpatentability of 338

¹ This Court should at least disregard paragraphs not cited in Masimo’s opposition (¶¶27-39, 37-42, 47, 70, 72-76, 82), which serve only to air personal grievances and beliefs.

claims from fifteen Masimo patents related to blood oxygen measurement. The 2023 trade secrets trial mentioned throughout Mr. Kiani's declaration was equally disastrous for Masimo. The judge granted Apple JMOL on half of Masimo's alleged trade secrets, *Apple Inc. v. Masimo Corp.*, No. 20-cv-00048, ECF No. 1724 (May 4, 2023), and—according to a jury note—all but one juror was prepared to vote in Apple's favor on the remainder, *id.* ECF No. 1713.

Mr. Kiani's attempts to denigrate Apple Watch are equally divorced from reality. The accuracy of Apple Watch's Blood Oxygen feature has been praised by medical journals, Reply-Add-25-41, and numerous medical professionals and organizations like the American Heart Association explained to the Commission the importance of Watch—including its pulse oximetry feature—to public health and medical research. Reply-Add-2-23.

At root, the Commission and Masimo ask this Court to endorse banning the importation and sale of a pioneering product made by a quintessentially American company that directly employs more than 90,000 employees—and supports the employment of hundreds of thousands of others—in the U.S. Worse, they take this position to protect Masimo's W1 watch, which concededly (1) did not exist when Masimo filed its complaint, (2) was not placed in the consumer channel, and (3) is sold only in *de minimis* quantities even now, well over two years after this

Investigation began on the false premise that Masimo had an established domestic industry.

ARGUMENT

I. LIKELIHOOD OF SUCCESS²

A. Apple Will Likely Prevail On Domestic Industry

Masimo has failed to identify an “actual article” that practices the asserted claims. Mot. 6-11. It is now undisputed the purported “article” depicted in the CAD drawings attached to Masimo’s Complaint never existed and even Masimo concedes the drawings “are not patent-practicing articles.” ITC-Opp. 5-6; Masimo-Opp. 6-7. Instead, the Commission and Masimo assert the law permits a complainant to establish a domestic industry *existed* at the time of complaint by pointing later to different items than what appears in the complaint (most of which did not exist when the Complaint was filed).³ Even the Commission cannot identify any precedent for this position. Rewarding a bait-and-switch approach renders the “actual article” requirement meaningless, granting complainants with CAD software and a future-product idea access to the Commission’s extraordinary injunctive powers.

² The suggestion (ITC-Opp. 1 n.2, Masimo-Opp. 11) that Apple is not challenging the Commission’s infringement findings is specious. *See* Mot. 6 n.4.

³ The Commission’s decision expressly declined to rely on a theory that Masimo was *in the process of* developing a domestic industry. Stay-Add-97.

Furthermore, neither the Commission nor Masimo identifies any authority that the Commission can find a domestic industry exists based solely on circumstantial evidence.⁴ That, however, is what happened here. There is no direct evidence that any of the eight “articles” Masimo proffered practiced the asserted claims.

“RevA” was the only alleged article identified by Masimo that existed when the Complaint was filed, Mot. 9, but it plainly does not practice the claims at issue. As the images in Apple’s opening brief show, it has no strap or other means of being “user worn” (as all remaining claims require). Mot. 9, 12.⁵

Equally important, nothing in the record showed RevA—or the RevD or the three RevE items—were *operational* (i.e., could actually measure blood oxygen) before the complaint’s filing. Mot. 10. Masimo introduced the items into evidence yet made *no attempt* to show live at the hearing or through recorded demonstrations that the “Rev” articles were configured to measure blood oxygen.

⁴ The cases cited permitted circumstantial evidence to prove facts in the control of others (a purported infringer (*Lucent, Moleculon*) and a third-party licensee (*Filament*)). That rationale makes no sense here, when the question is whether Masimo itself possessed a certain item.

⁵ The ALJ found RevA was “produced in discovery without a strap.” Stay-Add-243. The only strap-related evidence is vague testimony that RevA had Masimo Confidential Business Information ITC-Add-21.

To remedy this failure of proof, the ALJ (and by extension, the Commission) pointed to evidence that *different* “prototype devices” “*consistent with*” the specific RevA, RevD, and three RevE items allegedly measured blood oxygen. Mot. 10 (citing *inter alia* Stay-Add-221-222 & n.16). Indeed, Masimo has acknowledged that several devices with RevA sensors were not usable when the Complaint was filed. *See* Reply-Add-49, Reply-Add-55-56. The Commission and Masimo do not seriously dispute the lack of direct evidence. Instead, the Commission’s brief echoes the ALJ’s language. *E.g.*, ITC-Opp. 7 (“Mr. Al-Ali described internal testing of blood oxygen saturation using a device *consistent with*” RevD).⁶ While the Commission asserts “a RevE sensor” was tested before discovery, *id.* 8, the underlying cite confirms it was not one of the three RevE sensors identified in discovery as the actual article, Stay-Add-244 (ALJ finding “Mr. Al-Ali described testing of RevE devices (*though not the specific devices produced*)”).

The Commission’s chief response is to accuse Apple of “abandon[ing]” the position that RevA does not practice the claims. ITC-Opp 6 n.4; *see* Masimo-Opp 8. That is wrong, as explained above. Moreover, it is the Commission’s stay decision that abandoned any argument regarding why RevA (or RevD, or the RevE items) supports its domestic industry conclusion. The only specific reason that

⁶ Emphasis added in quotes throughout.

decision gave for rejecting Apple’s domestic industry arguments (including that RevA lacks a strap) was they raised questions of fact not law—a rule that cannot be squared with *Standard Havens*. Mot. 11. The Commission does not even attempt to defend that rationale.

In short, this case illustrates that the Commission has adopted an interpretation of “domestic industry” completely divorced from any reasonable meaning of that term. Apple respectfully submits it is likely to succeed in persuading the Court to restore the proper standards for Commission investigations, which would alone compel a judgment for Apple.

B. Apple Will Likely Prevail On Validity

1. **“User-worn.”** The Commission erred by requiring Apple to establish Lumidigm taught measuring blood oxygen at the wrist specifically. Mot. 11-14. This enablement issue did not arise *until* the ALJ’s decision, and Apple raised the ALJ’s error at the first available opportunity—its petition. *See* Reply-Add-59-64. The Commission is accordingly wrong (at 11) that Apple failed to timely raise this argument.

The Commission (at 12) disputes this Court has held that a patent challenger cannot be required to show the prior art enables more than the patent-at-issue. The Commission is again wrong. *See In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (rejecting argument prior art is not enabling when patent owner “did not

provide the type of detail in his specification he now argues is necessary in prior art references”); *accord In re Paulsen*, 30 F.3d 1475, 1481 n.9 (Fed. Cir. 1994).

The Commission ignores *Paulsen*, and while it argues *Epstein* should be limited to its facts, it provides no reason why that is so.⁷

Finally, the Commission (at 13) contends Apple created the problem by citing Lumidigm, which does not identify any specific embodiments worn at locations other than the wrist. However, it does not deny that (1) Lumidigm states its sensor can be included in any “portable electronic device” and (2) nothing in Lumidigm suggests the wristwatch embodiment could not be worn elsewhere on the body (e.g., upper arm or ankle).

2. “Windows” (Mot. 14-15). *First*, the Commission (at 15) misstates the record in suggesting Apple is making its *KSR* argument “for the first time.” Apple *prevailed* on this limitation before the ALJ, and thus had no reason to raise the issue in its petition to the Commission. Stay-Add-281-284.⁸ Masimo challenged the ALJ’s findings on “windows,” and Apple timely raised the *KSR*

⁷ The Commission’s lone authority (*Rasmusson*) supports Apple. It holds that the enablement standard is *lower* when assessing whether prior art anticipates an asserted claim than when deciding enablement under §112. 413 F.3d at 1325.

⁸ Masimo is wrong (at 14) that the ALJ ruled in its favor on this issue. Masimo cites the ruling on claim 22’s “within” limitation, which Apple’s motion addressed separately. Mot. 15. Neither the Commission nor Masimo substantively responds to the “within” argument.

point in its response to Masimo’s petition. Reply-Add-68-69, Reply-Add-76-77. *Second*, the Commission (at 16) and Masimo (at 15) dispute that a limited number of design alternatives exist for the “windows” limitation, but Apple’s expert identified only two, Mot. 14, and neither the Commission nor Masimo has pointed to further alternatives. *Finally*, the Commission (at 16) speculates a convex surface with separate embedded windows might be uncomfortable, but it is improper for the Commission to raise a “post hoc rationalization” on appeal. *Align Tech., Inc. v. ITC*, 771 F.3d 1317, 1324 (Fed. Cir. 2014).

C. Apple Will Likely Prevail On Laches

The Commission (at 17-19) and Masimo (at 17) ask this Court to adopt a novel waiver rule—i.e., that a movant that raises an issue in a succinct manner must suffer the same punishment as one that fails to raise it at all. No case law supports such a harsh approach, which is particularly inequitable here given the Commission’s final decision itself did not find waiver and provided its post hoc rationalization only in the stay decision.

Masimo (at 16-17) briefly argues the merits, but does not dispute that the chief reason why the ALJ found no delay was the mere fact that Masimo filed patent applications in the intervening time period *other* than the ones at issue here. That justification is insufficient to avoid laches. *E.g., Sonos, Inc. v. Google LLC*, 2023 WL 6542320, at *1-2, 11, 26-27 (N.D. Cal. Oct. 6, 2023) (laches applied

where patentee relied on “a daisy chain of continuation applications” to claim priority to a thirteen-year-old application).

II. IRREPARABLE HARM

The Commission and Masimo argue Apple’s reputational harm cannot be truly irreparable because Apple can still sell Apple Watch SE and other, non-Watch products. ITC-Opp. 18, 23; Masimo-Opp. 18. But the Commission’s final decision rejected the argument that SE is a reasonable substitute because it lacks important, life-saving features like ECG. Stay-Add-122 n.65. And neither the Commission nor Masimo explains why Apple’s ability to sell, e.g., iPhones has any bearing on this case.

The Commission and Masimo also contend Apple has failed to present sufficient detail establishing its irreparable harm. ITC-Opp. 20-21; Masimo-Opp. 20-21. But Apple presented the same quantum of evidence this Court found sufficient in *Metalcraft*. Mot. 19 & n.9. Masimo has no answer to this case law; it does not even cite *Metalcraft*. While the Commission asserts *Metalcraft*’s holding was limited to the “record in that case,” it provides no meaningful reason why that is so given that there was comparable evidence in this case.⁹

⁹ While the declarations Apple previously cited were originally submitted to show harm to the public, there is no reason why the same evidence cannot serve two purposes.

Finally, the Commission and Masimo contend Apple will not suffer irreparable harm if CBP approves a redesigned version of the accused Watch products. ITC-Opp. 21; Masimo-Opp. 19. While a redesign was approved on Friday, it **confidential redesign information**.¹⁰ This means Apple will continue to suffer reputational harm from being unable to provide consumers with a fully-featured Apple Watch product, including **confidential redesign information**.

III. BALANCE OF EQUITIES

Masimo still has no meaningful competing product to Apple Watch—i.e., Masimo sells the W1 watch in *de minimis* quantities in the U.S., it has not put the W1 in the consumer (as opposed to clinical) channel, and Masimo’s “Freedom” watch has never been sold. *See* Stay-Add-11-12; *see also* Kiani Decl. ¶¶19-22. Moreover, neither Masimo nor the Commission disputes the lone, generic “harm” the Commission identified (that Masimo will be unable to make full use of its patents) is insufficient to warrant denying Apple’s motion. Mot. 20-21.

Instead, Masimo and the Commission advance new and meritless theories of harm. For example, the suggestion (ITC-Opp. 21; Masimo-Opp. 21) that *Masimo* will suffer harm from competing against an infringing product overlooks the undisputed fact that Masimo does not sell its purportedly competing product in

¹⁰ Masimo’s 28(j) letter improperly quotes a phrase from a non-public document, language that Apple has uniformly marked as confidential with one inadvertent oversight.

more than *de minimis* amounts. Masimo's other theories of harm (e.g., a stay will affect public perceptions of pulse oximetry and somehow demoralize its employees) are unsupported by case law and suffer from the same basic factual flaw—Masimo sells no competing product in meaningful amounts such that the absence of Apple Watch from the market would affect perception of Masimo's technology. And while Masimo argues that a stay would appear to validate Apple's legal position, Masimo successfully urged the Commission to reject the same basic argument below when it was advanced by Apple (i.e., allowing the orders to go into effect would validate Masimo's position). *See* Stay-Add-11; Reply-Add-82. At minimum, Masimo is estopped from taking a contrary position. *See Trustees v. United States*, 593 F.3d 1346, 1354 (Fed. Cir. 2010).

IV. PUBLIC INTEREST

Neither the Commission nor Masimo disputes the public interest factor for a stay pending appeal is easier to satisfy than the *statutory* public interest factors under Section 337. *See* Mot. 23. However, both parties rely almost exclusively on the Commission's statutory findings without explaining why the same analysis applies to the different legal standard used for a stay. *See* ITC-Opp. 22-23; Masimo-Opp. 22-26.

The Commission and Masimo also point to the Commission's conclusion that substitutes are available for the flagship Apple Watch models. But the

Commission has already held the only Apple Watch all agree is non-infringing (the SE) lacks ECG and therefore is not a “reasonable substitute,” Stay-Add-122 n.65, and other devices lack the unique combination of health, wellness, and connectivity features included in Apple’s flagship Watch products. Moreover, Apple’s redesigned Watch **confidential redesign information**, meaning not entering a stay would impair the public’s use of that feature.

Finally, the Commission and Masimo note the Commission’s final decision includes a limited repair/replacement exception. The Commission’s stay decision did not rest on that ground, likely because the exception applies only to a discrete class of customers, Stay-Add-135-136. Anyone beyond a relatively recent purchaser or one who has paid for enhanced protection may have no replacement option. That result will hurt new consumers (who will be deprived of an exceptional product) and medical researchers (who will be impeded from enrolling new participants in ongoing studies).

Respectfully submitted,

/s/ Mark D. Selwyn

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January 15, 2024

CERTIFICATE OF INTEREST

Counsel for Appellant Apple Inc. certifies the following:

1. Represented Entities. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

Apple Inc.

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

None.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

None.

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

WILMER CUTLER PICKERING HALE AND DORR LLP: Brittany Blueitt Amadi, Thomas Anderson, James Bor-Zale, Alison Burton, David L. Cavanaugh, Jennifer Charlton (former), Jonathan A. Cox, Ravi Deol, Kim Do, Laura Donovan, Sydney Donovan, Michael Esch (former), Nina Garcia, Richard Goldenberg (former), David Gringer, Vikram Iyer, Brian Jacobsmeyer (former), Julius Jefferson (former), Rauvin Johl, Jennifer John (former), Joshua Lerner, James Lyons, Lauren Mandell, Courtney Merrill, Zach Nemtzow, Henry Nikogosyan, Richard W. O'Neill, Nora Q.E. Passamaneck, Allison Que, David Ross, Cristina Salcedo, Hannah Santasawatkul, Emily Scherker, Michaela P. Sewall, Labdhi Sheth, Linda Sun (former), Jose Valenzuela, Cynthia D. Vreeland, Yifan (Ivan) Wang, Amy K. Wigmore

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WEIL, GOTSHAL & MANGES LLP: Mark Perry

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☒ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). Please do not duplicate information. This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

Notice appears at C.A. Docket 4.

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None.

Dated: January 15, 2024

/s/ Mark D. Sewlyn
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ADDENDUM

No. 2024-1285

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors,

On Appeal from the United States International Trade Commission
in Investigation No. 337-TA-1276

**DECLARATION OF MARK D. SELWYN IN FURTHER SUPPORT OF
APPELLANT APPLE INC.'S EMERGENCY MOTION TO STAY
ENFORCEMENT OF ITC'S ORDERS PENDING REVIEW**

I, Mark D. Selwyn, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am a partner at Wilmer Cutler Pickering Hale and Dorr LLP, counsel to Appellant Apple Inc. in the above-captioned appeal. I have personal knowledge of the facts set forth below.

2. Attached hereto as Exhibit 1 is a true and correct copy of the Statement of Non-Party American Heart Association on the Public Interest of the Recommended Remedial Orders But Not in Support of Any Party, dated March 1, 2023, filed in Investigation No. 337-TA-1276, *In the Matter of Certain Light-Based*

Physiological Measurement Devices and Components Thereof (hereinafter “1276 Investigation”).

3. Attached hereto as Exhibit 2 is a true and correct copy of a declaration of Dr. Richard Milani, dated March 1, 2023, filed in the 1276 Investigation.

4. Attached hereto as Exhibit 3 is a true and correct copy of a letter from Dr. Stephen Ruoss, dated February 21, 2023, filed in the 1276 Investigation.

5. Attached hereto as Exhibit 4 is a true and correct copy of a letter from Dr. Russell Bowler, filed in the 1276 Investigation on February 17, 2023.

6. Attached hereto as Exhibit 5 is a true and correct copy of an article by Carmen Spaccarotella, *et al.*, titled “Assessment Of Non-Invasive Measurements Of Oxygen Saturation And Heart Rate With An Apple Smartwatch: Comparison With A Standard Pulse Oximeter,” published on March 8, 2022 in the *Journal of Clinical Medicine*, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8951323/>, which states on page 5 that “[t]he major result of the present study is that the measurements of SpO2 obtained using the Apple Watch are reliable compared to the standard pulse oximetry technique in patients with cardiovascular disease, lung disease, and healthy subjects.”

7. Attached hereto as Exhibit 6 is a true and correct copy of an article by Jakub Rafl, *et al.*, titled “Commercial Smartwatch With Pulse Oximeter Detects Short-time Hypoxemia As Well As Standard Medical-grade Device: Validation

Study,” published on October 11, 2022 in *Digital Health*, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9554125/>, which states on page 4 that “SpO2 measurement by Apple Watch Series 6, a consumer product, did not differ on average from SpO2 measurement by Masimo Radical-7 pulse oximeter, a medical device. The average absolute difference or bias between smartwatch and oximeter SpO2 measurements, evaluated for all pooled data, in two ranges and at the individual study times, was less than 1% SpO2.”

8. Attached hereto as Exhibit 7 is a true and correct excerpt from Complainants’ Sixth Supplemental Responses and Objections to Apple Inc.’s Seventh Set of Interrogatories (82, 90), dated April 3, 2022, which was trial exhibit RX-1183C in the 1276 Investigation. This exhibit contains information that Complainants designated as Confidential Business Information pursuant to the Administrative Protective Order in the 1276 Investigation. No public version of this document is currently available.

9. Attached hereto as Exhibit 8 is a true and correct excerpt from the public version of Respondent Apple Inc.’s January 23, 2023 Petition for Review of the Initial Determination of Violation of Section 337 filed in the 1276 Investigation.

10. Attached hereto as Exhibit 9 is a true and correct excerpt from the public version of Complainants’ January 23, 2023 Petition for Review of the Initial Determination of Violation of Section 337 filed in the 1276 Investigation.

11. Attached hereto as Exhibit 10 is a true and correct excerpt from the public version of Respondent Apple Inc.'s January 31, 2023 Response to Complainants' Petition for Review filed in the 1276 Investigation.

12. Attached hereto as Exhibit 11 is a true and correct excerpt from the public version of Complainants' November 9, 2023 Opposition to Respondent Apple Inc.'s Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal and/or in Light of the Potential Government Shutdown filed in the 1276 Investigation.

Executed on: January 15, 2024

/s/ Mark D. Selwyn
Mark D. Selwyn

TABLE OF CONTENTS

Ex.	Document	Pages
1	Statement of Non-Party American Heart Association on the Public Interest of the Recommended Remedial Orders But Not in Support of Any Party, March 1, 2023,	Reply-Add-1-10
2	Declaration of Dr. Richard Milani, March 1, 2023	Reply-Add-11-18
3	Letter from Dr. Stephen Ruoss, February 21, 2023	Reply-Add-19-21
4	Letter from Dr. Russell Bowler, February 17, 2023	Reply-Add-22-23
5	Carmen Spaccarotella, et al., “Assessment Of Non-Invasive Measurements Of Oxygen Saturation And Heart Rate With An Apple Smartwatch: Comparison With A Standard Pulse Oximeter,” <i>Journal of Clinical Medicine</i> , March 8, 2022	Reply-Add-24-31
6	Jakub Rafl, et al., “Commercial Smartwatch With Pulse Oximeter Detects Short-time Hypoxemia As Well As Standard Medical-grade Device: Validation Study,” <i>Digital Health</i> , October 11, 2022	Reply-Add-32-41
7	Complainants’ Sixth Supplemental Responses and Objections to Apple Inc.’s Seventh Set of Interrogatories (82, 90) (RX-1183C), April 3, 2022, excerpted	Reply-Add-42-56
8	Respondent Apple Inc.’s Petition for Review of the Initial Determination of Violation of Section 337, January 23, 2023, excerpted	Reply-Add-57-65
9	Complainants’ Petition for Review of the Initial Determination of Violation of Section 337, January 23, 2023, excerpted	Reply-Add-66-71
10	Respondent Apple Inc.’s Response to Complainants’ Petition for Review, January 31, 2023, excerpted	Reply-Add-72-78

Ex.	Document	Pages
11	Complainants' Opposition to Respondent Apple Inc.'s Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal and/or in Light of the Potential Government Shutdown, November 9, 2023, excerpted	Reply-Add-79-84

RULE 25.1(e)(1)(B) STATEMENT

The material omitted from Addendum pages Reply-Add-43-56 contains information that Complainants Masimo Corporation and Cercacor Laboratories, Inc. designated as Confidential Business Information under the Administrative Protective Order in effect in ITC Investigation No. 1276.

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**

Inv. No. 337-TA-1276

ORDER NO. 1: PROTECTIVE ORDER

(August 18, 2021)

WHEREAS, documents and information may be sought, produced or exhibited by and among the parties to the above captioned proceeding, which materials relate to trade secrets or other confidential research, development or commercial information, as such terms are used in the Commission's Rules, 19 C.F.R. § 210.5;

IT IS HEREBY ORDERED THAT:

1. Confidential business information is information which concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, or other information of commercial value, the disclosure of which is likely to have the effect of either (i) impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions; or (ii) causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such

information. The term “confidential business information” includes “proprietary information” within the meaning of section 777(b) of the Tariff Act of 1930 (19 U.S.C. § 1677f(b)).

2(a). Any information submitted, in pre hearing discovery or in a pleading, motion, or response to a motion either voluntarily or pursuant to order, in this investigation, which is asserted by a supplier to contain or constitute confidential business information shall be so designated by such supplier in writing, or orally at a deposition, conference or hearing, and shall be segregated from other information being submitted. Documents shall be clearly and prominently marked on their face with the legend: “CONFIDENTIAL BUSINESS INFORMATION, SUBJECT TO PROTECTIVE ORDER,” or a comparable notice. Such information, whether submitted in writing or in oral testimony, shall be treated in accordance with the terms of this protective order.

(b). The Administrative Law Judge or the Commission may determine that information alleged to be confidential is not confidential, or that its disclosure is necessary for the proper disposition of the proceeding, before, during or after the close of a hearing herein. If such a determination is made by the Administrative Law Judge or the Commission, opportunity shall be provided to the supplier of such information to argue its confidentiality prior to the time of such ruling.

3. In the absence of written permission from the supplier or an order by the Commission or the Administrative Law Judge, any confidential documents or business information submitted in accordance with the provisions of paragraph 2 above shall not be disclosed to any person other than: (i) outside counsel for parties to this investigation, including necessary secretarial and support personnel assisting such counsel; (ii) qualified persons taking testimony involving such documents or information and necessary stenographic and clerical personnel thereof; (iii)

technical experts and their staff who are employed for the purposes of this litigation (unless they are otherwise employed by, consultants to, or otherwise affiliated with a non-governmental party, or are employees of any domestic or foreign manufacturer, wholesaler, retailer, or distributor of the products, devices or component parts which are the subject of this investigation); (iv) the Commission, the Administrative Law Judge, the Commission staff, and personnel of any governmental agency as authorized by the Commission; (v) the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this investigation or related proceedings, or (b) in internal investigations, audits, reviews, evaluations relating to the programs, personnel, and operations of the Commission including under to 5 U.S.C. Appendix 3; and (vi) U.S. government employees and contract personnel, solely for cybersecurity purposes.¹

4. Confidential business information submitted in accordance with the provisions of paragraph 2 above shall not be made available to any person designated in paragraph 3(i)² and (iii) unless he or she shall have first read this order and shall have agreed, by letter filed with the Secretary of this Commission: (i) to be bound by the terms thereof; (ii) not to reveal such confidential business information to anyone other than another person designated in paragraph 3; and (iii) to utilize such confidential business information solely for purposes of this investigation.

The letter shall also include the following acknowledgement:

I, the undersigned, on behalf of _____, acknowledge that information submitted for purposes of this Investigation may be disclosed to and used:

(i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in

¹ See Commission Administrative Order 16-01 (Nov. 7, 2015).

² Necessary secretarial and support personnel assisting counsel need not sign onto the protective order themselves because they are covered by counsel's signing onto the protective order.

internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or

(ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. I understand that all contract personnel will sign appropriate nondisclosure agreements.

5. If the Commission or the Administrative Law Judge orders, or if the supplier and all parties to the investigation agree, that access to, or dissemination of information submitted as confidential business information shall be made to persons not included in paragraph 3 above, such matter shall only be accessible to, or disseminated to, such persons based upon the conditions pertaining to, and obligations arising from this order, and such persons shall be considered subject to it, unless the Commission or the Administrative Law Judge finds that the information is not confidential business information as defined in paragraph 1 thereof.

6. (a). Any confidential business information submitted to the Commission or the Administrative Law Judge in connection with a motion or other proceeding within the purview of this investigation shall be submitted under seal pursuant to paragraph 2 above. Any portion of a transcript in connection with this investigation containing any confidential business information submitted pursuant to paragraph 2 above shall be bound separately and filed under seal. When any confidential business information submitted in accordance with paragraph 2 above is included in an authorized transcript of a deposition or exhibits thereto, arrangements shall be made with the court reporter taking the deposition to bind such confidential portions and separately label them "CONFIDENTIAL BUSINESS INFORMATION, SUBJECT TO PROTECTIVE ORDER." Before a court reporter or translator receives any such information, he or she shall have first read this order and shall have agreed in writing to be bound by the terms thereof. Alternatively, he or she shall sign the agreement included as Attachment A hereto.

Copies of each such signed agreement shall be provided to the supplier of such confidential business information and the Secretary of the Commission.

(b). Submitters³ are strongly encouraged to encrypt nonpublic documents that are electronically transmitted to the Commission to protect your sensitive information from unauthorized disclosure. The USITC secure drop-box system and the Electronic Document Information System (EDIS) use Federal Information Processing Standards (FIPS) 140-2 cryptographic algorithms to encrypt data in transit. Submitting your nonpublic documents by a means that does not use these encryption algorithms (such as by email) may subject your firm's nonpublic information to unauthorized disclosure during transmission. If you choose a non-encrypted method of electronic transmission, the Commission warns you that the risk of such possible unauthorized disclosure is assumed by you and not by the Commission.

7. The restrictions upon, and obligations accruing to, persons who become subject to this order shall not apply to any information submitted in accordance with paragraph 2 above to which the person asserting the confidential status thereof agrees in writing, or the Commission or the Administrative Law Judge rules, after an opportunity for hearing, was publicly known at the time it was supplied to the receiving party or has since become publicly known through no fault of the receiving party.

8. The Commission, the Administrative Law Judge, and the Commission investigative attorney acknowledge that any document or information submitted as confidential business information pursuant to paragraph 2 above is to be treated as such within the meaning of 5 U.S.C. § 552(b)(4) and 18 U.S.C. § 1905, subject to a contrary ruling, after hearing, by the

³ "Submitters" of confidential business information are the same as "suppliers" of confidential business information as that term is used in the context of this order. *See* Commission Administrative Order 16-01 (Nov. 7, 2015).

Commission or its Freedom of Information Act Officer, or the Administrative Law Judge. When such information is made part of a pleading or is offered into the evidentiary record, the data set forth in 19 C.F.R. § 201.6 must be provided except during the time that the proceeding is pending before the Administrative Law Judge. During that time, the party offering the confidential business information must, upon request, provide a statement as to the claimed basis for its confidentiality.

9. Unless a designation of confidentiality has been withdrawn, or a determination has been made by the Commission or the Administrative Law Judge that information designated as confidential, is no longer confidential, the Commission, the Administrative Law Judge, and the Commission investigative attorney shall take all necessary and proper steps to preserve the confidentiality of, and to protect each supplier's rights with respect to, any confidential business information designated by the supplier in accordance with paragraph 2 above, including, without limitation: (a) notifying the supplier promptly of (i) any inquiry or request by anyone for the substance of or access to such confidential business information, other than those authorized pursuant to this order, under the Freedom of Information Act, as amended (5 U.S.C. § 552) and (ii) any proposal to redesignate or make public any such confidential business information; and (b) providing the supplier at least seven days after receipt of such inquiry or request within which to take action before the Commission, its Freedom of Information Act Officer, or the Administrative Law Judge, or otherwise to preserve the confidentiality of and to protect its rights in, and to, such confidential business information.

10. If while an investigation is before the Administrative Law Judge, a party to this order who is to be a recipient of any business information designated as confidential and submitted in accordance with paragraph 2 disagrees with respect to such a designation, in full or in part, it

shall notify the supplier in writing, and they will thereupon confer as to the status of the subject information proffered within the context of this order. If prior to, or at the time of such a conference, the supplier withdraws its designation of such information as being subject to this order, but nonetheless submits such information for purposes of the investigation; such supplier shall express the withdrawal, in writing, and serve such withdrawal upon all parties and the Administrative Law Judge. If the recipient and supplier are unable to concur upon the status of the subject information submitted as confidential business information within ten days from the date of notification of such disagreement, any party to this order may raise the issue of the designation of such a status to the Administrative Law Judge who will rule upon the matter. The Administrative Law Judge may sua sponte question the designation of the confidential status of any information and, after opportunity for hearing, may remove the confidentiality designation.

11. No less than 10 days (or any other period of time designated by the Administrative Law Judge) prior to the initial disclosure to a proposed expert of any confidential information submitted in accordance with paragraph 2, the party proposing to use such expert shall submit in writing the name of such proposed expert and his or her educational and detailed employment history to the supplier. If the supplier objects to the disclosure of such confidential business information to such proposed expert as inconsistent with the language or intent of this order or on other grounds, it shall notify the recipient in writing of its objection and the grounds therefore prior to the initial disclosure. If the dispute is not resolved on an informal basis within ten days of receipt of such notice of objections, the supplier shall submit immediately each objection to the Administrative Law Judge for a ruling. If the investigation is before the Commission the matter shall be submitted to the Commission for resolution. The submission of such confidential business information to such proposed expert shall be withheld pending the ruling of the

Commission or the Administrative Law Judge. The terms of this paragraph shall be inapplicable to experts within the Commission or to experts from other governmental agencies who are consulted with or used by the Commission.

12. If confidential business information submitted in accordance with paragraph 2 is disclosed to any person other than in the manner authorized by this protective order, the party responsible for the disclosure must immediately bring all pertinent facts relating to such disclosure to the attention of the supplier and the Administrative Law Judge and, without prejudice to other rights and remedies of the supplier, make every effort to prevent further disclosure by it or by the person who was the recipient of such information.

13. Nothing in this order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action with respect to any ruling made by the Commission, its Freedom of Information Act Officer, or the Administrative Law Judge concerning the issue of the status of confidential business information.


14. Upon final termination of this investigation, each recipient of confidential business information that is subject to this order shall assemble and return to the supplier all items containing such information submitted in accordance with paragraph 2 above, including all copies of such matter which may have been made. Alternatively, the parties subject to this order may, with the written consent of the supplier, destroy all items containing confidential business information and certify to the supplier (or his counsel) that such destruction has taken place. This paragraph shall not apply to the Commission, including its investigative attorney, and the Administrative Law Judge, which shall retain such material pursuant to statutory requirements and for other recordkeeping purposes, but may destroy such material (including electronic media containing such information) in its possession which it regards as surplusage.

Notwithstanding the above paragraph, confidential business information may be transmitted to a district court pursuant to Commission Rule 210.5(c).

15. If any confidential business information which is supplied in accordance with paragraph 2 above is supplied by a nonparty to this investigation, such a nonparty shall be considered a "supplier" as that term is used in the context of this order.

16. Each nonparty supplier shall be provided a copy of this order by the party seeking information from said supplier.

17. The Secretary shall serve a copy of this order upon all parties.



Charles E. Bullock
Chief Administrative Law Judge

Attachment A

NONDISCLOSURE AGREEMENT FOR REPORTER/STENOGRAPHER/TRANSLATOR

I, _____, do solemnly swear or affirm that I will not divulge any information communicated to me in any confidential portion of the investigation or hearing
CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF
in the matter of *Certain* _____, Investigation No. 337-TA- 1276 except as permitted in the protective order issued in this case. I will not directly or indirectly use, or allow the use of such information for any purpose other than that directly associated with my official duties in this case.

Further, I will not by direct action, discussion, recommendation, or suggestion to any person reveal the nature or content of any information communicated during any confidential portion of the investigation or hearing in this case.

I also affirm that I do not hold any position or official relationship with any of the participants in said investigation.

I am aware that the unauthorized use or conveyance of information as specified above is a violation of the Federal Criminal Code and punishable by a fine of up to \$10,000, imprisonment of up to ten (10) years, or both.

Signed _____

Dated _____

Firm or affiliation _____

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND COMPONENTS
THEREOF**

Inv. No. 337-TA-1276

Certificate of Service – Page 1

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served upon the following parties as indicated, on **August 18, 2021**.



Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

**On Behalf of Complainants Masimo Corporation and
Cercacor Laboratories, Inc.:**

Jonathan Bachand, Esq.
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Avenue, NW, Suite 900
Washington, DC 20006
Email: Jonathan.Bachand@knobbe.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download

Respondent:

Apple Inc.
One Apple Park Way
Cupertino, CA 95014

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Service to Be
Completed by Complainants

EXHIBIT 1

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**In the Matter of
CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**

Investigation No. 337-TA-1276

**STATEMENT OF NON-PARTY
AMERICAN HEART ASSOCIATION
ON THE PUBLIC INTEREST OF THE RECOMMENDED REMEDIAL ORDERS
BUT NOT IN SUPPORT OF ANY PARTY**

I. INTRODUCTION

The American Heart Association, Inc. (the “AHA”) believes the ALJ’s recommended remedial orders would harm scientific research, healthcare consumers, and healthcare providers in the U.S. Accordingly, the AHA urges the Commission to tailor any remedial orders to allow researchers adequate time to complete ongoing research projects and transition to new protocols with devices not subject to any limited exclusion order (“LEO”) or cease and desist order (“CDO”).

II. AHA’S INTEREST IN THE RECOMMENDED REMEDIAL ORDERS

As the nation’s oldest and largest voluntary health organization, the AHA strives to be a relentless force for a world of longer, healthier lives with a particular emphasis on a broad-range of cardiovascular and stroke-related health topics. Working at the intersection of science and technology is the AHA’s Center for Health Technology and Innovation (“CHTI”), which encourages the use of digital health solutions to lower healthcare costs, increase patient engagement and improve healthcare outcomes for patients and consumers. The AHA and the CHTI fund vital scientific research, bringing together research institutions, technology and digital health companies in research programs seeking new applications of technology to improve overall consumer well-being and to provide affordable preventive, diagnostic and treatment measures.

The AHA has a research relationship with the Respondent in the Investigation. It has no position on the merits of the investigation and supports none of the private parties. However, we are concerned about the direct, harmful, near-term impact that the recommended LEO and CDO would have on healthcare consumers, healthcare providers and scientific researchers in the U.S.

We understand the ALJ’s recommends an LEO with a standard certification provision and a CDO with respect to Apple Watch Series 6, 7, and certain prototype products referred to as Next Generation (“Devices”). The Devices play a unique role in research of interest to the AHA and healthcare consumers. As prevalent consumer devices owned for reasons other than just their cardiac-data-related technologies, the user population is sufficiently large and representative of the

subjects researchers seek to recruit, that they allow studies to be fully enrolled cost-effectively, facilitating research the AHA promotes. Additionally, the Devices and their users allow for types of research to occur that might not otherwise be attempted, or only attempted less frequently or with smaller sample sizes. Notably, they facilitate research into whether cardiac health outcomes can be improved by consumer devices detecting and triggering interventions. As the novelty of these devices has waned since their introduction, researchers benefit from and, to some extent, rely on the extent of consumer adoption of the Devices to design and recruit for research studies.

III. THE RECOMMENDED REMEDIAL ORDERS JEOPARDIZE CARDIOVASCULAR AND OTHER SCIENTIFIC RESEARCH

The AHA encourages the development and proliferation of reliable consumer healthcare devices that assist patients and healthcare consumers in better understanding and managing their own health and well-being, in communicating with their healthcare providers, and participating in valuable and decentralized health research. Our aim is to build new types of healthcare insights to improve our understanding of how technology-based devices and solutions can best impact care.

A. The Devices Provide Important Data Acquisition and Reporting Technology For Basic Scientific Research by Numerous Researchers

The AHA is currently collaborating on two research studies involving Apple Watches, one is a Vanderbilt University study related to Atrial Fibrillation (“AF”)¹ and the other a Johns Hopkins University study related to Coronary Artery Disease and cardiac rehabilitation.² These studies utilize data obtained from study participants while wearing Apple Watches, including the Devices. Other institutions are involved in similar research. Data available from the website ClinicalTrials.gov indicates there are several U.S. clinical trials that are currently active, recruiting,

¹ See https://clinicaltrials.gov/ct2/show/NCT04433091?term=%22Apple+Watch%22+AND+%28%22series%22+OR+%22ECG%22%29&recrs=abdf&map_cntry=US&draw=2&rank=8.

² See <https://clinicaltrials.gov/ct2/show/NCT05238103?term=%22Apple+Watch%22&recrs=abdf&cntry=US&draw=4&rank=30>.

or planned involving various Apple Watch Series, including the Devices.³ These include ECG studies by Yale University⁴ and the Mayo Clinic;⁵ a hypertension study by Stanford University;⁶ an AF study by the University of Oklahoma;⁷ and two heart failure studies by Biofourmis Singapore Pte Ltd.⁸ and by Tufts Medical Center.⁹ The AHA believes these studies utilize Device features other than the pulse oximetry feature at issue in the investigation; however, the ALJ's recommended remedial orders would nonetheless impact usage of the Devices in these studies.

The Devices provide a combination of clinically-interesting technological features and ongoing consumer prevalence *in a single wearable* that makes them a very attractive research platform. Additionally, an aim of some of that research is to investigate if consumer health can be improved via data from a consumer-worn device, such as the Devices, prompting interventions through the device or otherwise. The AHA is not aware of alternative devices available in volume in the U.S. that provide the same combination of attributes to researchers and consumers.

B. Requiring Researchers to Change Devices Would Jeopardize the Scientific Merit of Ongoing and Past Research and Waste Investments Made

Clinical and other scientific research requires months or years of planning, including design of research protocols and study objectives, interaction with governing bodies and collaborators,

³ See <https://clinicaltrials.gov/ct2/results?cond=&term=%22Apple+Watch%22&cntry=US&state=&city=&dist=&Search=Search&recrs=a&recrs=b&recrs=d&recrs=f> (last visited 2/21/2023).

⁴ See <https://clinicaltrials.gov/ct2/show/NCT04468321?term=%22Apple+Watch%22+AND+%28%22Series%22+or+%22atrial%22%29&recrs=abdf&draw=2&rank=4>.

⁵ See https://clinicaltrials.gov/ct2/show/NCT05324566?term=%22Apple+Watch%22+AND+%28%22series%22+OR+%22ECG%22%29&recrs=abdf&map_cntry=US&draw=2&rank=1.

⁶ See <https://clinicaltrials.gov/ct2/show/NCT03893500?term=%22Apple+Watch%22&recrs=abdf&cntry=US&draw=3&rank=12>.

⁷ See <https://clinicaltrials.gov/ct2/show/NCT05172765?term=%22Apple+Watch%22&recrs=abdf&cntry=US&draw=4&rank=28>.

⁸ See <https://clinicaltrials.gov/ct2/show/NCT04191356?term=%22Apple+Watch%22&recrs=abdf&cntry=US&draw=5&rank=38>.

⁹ See <https://clinicaltrials.gov/ct2/show/NCT04510779?term=%22Apple+Watch%22&recrs=abdf&cntry=US&draw=2&rank=2>.

enrolling subjects, and procuring necessary materials. Significant investment of time, money, and other resources have been made in the research involving the Devices in which the AHA has been involved, and we believe in other research.

For ongoing studies that are recruiting or those that have already been designed involving the Devices, the recommended remedial orders could jeopardize their scientific merit and cause waste of resources spent for the studies. Of course, the design of research protocols seeks to control for extraneous influences. If Apple Watch data in ongoing research could no longer be obtained because new participants had to use different devices as a result of the LEO or CDO, then questions about comparability of data before and after the device change likely would arise, if it were even possible to continue the study. This risks loss of some or all of the statistical power of gathered data and resulting scientific merit of the study. Studies planned for extended periods (the Vanderbilt study, for example, lists a 4 year time frame through May 2024) will likely be negatively impacted by a remedial order requiring switching mid-study to a new device. Similarly, for studies that have been designed, funded, and are recruiting now, or nearly so, switching devices risks requiring re-design of the study and waste of resources expended to date.

IV. THE COMMISSION SHOULD TAILOR ANY REMEDIAL ORDERS TO ALLOW FOR ONGOING RESEARCH AND CONSUMER ACCESS

The AHA believes that public interest is best served by keeping any current products on the market that contain electrocardiogram, heart rate monitoring, irregular heart rate notification and supporting features combined in some form. The devices currently on the market with verified accuracy are important to consumers, healthcare providers and researchers involved in assessing the impact of those devices to improve patient understanding, health, and outcomes.

From the AHA's perspective, the Devices are not just a pure technical component used in clinical research. Part of their interest is that they are widely used consumer devices that provide technologies enabling collection and reporting of data of clinical interest. The prevalence of these

devices among consumers not only helps provide research recruits but also helps investigate if a mass consumer device can be used to intervene to improve health outcomes by acquiring data used to (help) detect them. The AHA does not believe that adopting remedial orders requiring certifications by researchers for devices sought to be imported would adequately protect the interests with which it is concerned. *See Commission Opinion (Revised) in Certain Microfluidic Devices*, Inv. 337-TA-1068, at 22–48 (January 10, 2020). As explained above, part of the significance of the Devices is that they are a prevalent consumer device, not just a technical input used by researchers. A standard certification provision included in any LEO issued requiring researchers to indicate that certain Apple Watches sought to be imported were destined for a particular study or trial by certification would not reflect how those devices are used in the type of research the AHA promotes and wishes to see continue and would place a burden on the researchers to undertake the necessary analysis to determine if the certification is proper, further negatively impacting the ability to continue with on-going and already planned research.

For the reasons explained above, the AHA urges the Commission to tailor any remedial orders to ensure the supply of the Devices in the U.S. remain undisturbed over a sufficient time period for ongoing research to be completed and for upcoming research to transition to alternative devices that it expects would be brought to market without significant waste of resources on that research or significant delay in undertaking future research. The AHA believes the time period necessary for that transition to be a year or more.

If it would be helpful to the Commission, the AHA would be happy to provide additional details or information regarding the comments made above.

Date: March 1, 2023

Respectfully submitted,

/s/ Patrick Wayte

American Heart Association, Inc.

Center for Health Technology and Innovation

By and through counsel:

/s/ Robin L. Barnes
Robin L. Barnes

SCHEEF & STONE, LLP
2600 Network Blvd., Suite 400
Frisco, Texas 75034
(214) 706-4233 Telephone
(214) 706-4242 Facsimile
robin.barnes@solidcounsel.com

**In the Matter of Certain Light-Based Physiological Measurement
Devices and Components Thereof**

Inv. No. 337-TA-1276

CERTIFICATE OF SERVICE

I, Nicole Isenhardt, hereby certify that true and correct copies of the foregoing, Statement of Non-Party American Heart Association on the Public Interest of the Recommended Remedial Orders But Not in Support of Any Party, have been filed and served on this 1st day of March 2023, on the following in the manner indicated:

Secretary – U.S. International Trade Commission	
The Honorable Katherine M. Hiner Acting Secretary to the Commission U.S. International Trade Commission 500 E Street, SW, Room 112 Washington, DC 20436	<input checked="" type="checkbox"/> Via Electronic Filing [EDIS] <input type="checkbox"/> Via Hand Delivery (2 Copies) <input type="checkbox"/> Via Overnight Delivery
Administrative Law Judge – U.S. International Trade Commission	
The Honorable Monica Bhattacharyya U.S. International Trade Commission 500 E Street, S.W., Room 317 Washington, D.C. 20436	<input type="checkbox"/> Via Hand Delivery (2 Copies) <input type="checkbox"/> Via Overnight Delivery <input type="checkbox"/> Via Facsimile <input checked="" type="checkbox"/> Via Electronic Mail to edward.jou@usitc.gov; Bhattacharyya337@usitc.gov
Counsel for Claimants Masimo Corporation and Cercacor Laboratories, Inc.	
Stephen C. Jensen Joseph R. Re Sheila N. Swaroop Ted. M. Cannon Alan G. Laquer Kendall M. Loebbaka KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 Main Street Fourteenth Floor Irvine, CA 92614 William R. Zimmerman Jonathan E. Bachand KNOBBE, MARTENS, OLSON & BEAR, LLP 1717 Pennsylvania Avenue N.W., Suite 900 Washington, DC 20006 Brian C. Horne KNOBBE, MARTENS, OLSON & BEAR, LLP	<input type="checkbox"/> Via Hand Delivery (2 Copies) <input type="checkbox"/> Via Overnight Delivery <input type="checkbox"/> Via Facsimile <input checked="" type="checkbox"/> Via Electronic Mail to masimo.appleitc@knobbe.com

1925 Century Park East Suite 600 Los Angeles, CA 90067	
Counsel for Respondent Apple, Inc.	
Michael Esch David Cavanaugh WILMER CUTLER PICKERING HALE AND DORR LLP 2100 Pennsylvania Avenue, NW Washington, DC 20037 Mark Selwyn WILMER CUTLER PICKERING HALE AND DORR LLP 2600 El Camino Real Suite 400 Palo Alto, California 94306 Joseph Mueller Richard Goldenberg Sarah Frazier WILMER CUTLER PICKERING HALE AND DORR LLP 60 State Street Boston, Massachusetts 02109	<input type="checkbox"/> Via Hand Delivery (2 Copies) <input type="checkbox"/> Via Overnight Delivery <input type="checkbox"/> Via Facsimile <input checked="" type="checkbox"/> Via Electronic Mail to WHApple-Masimo1276ServiceList@wilmerhale.com

March 1, 2023

/s/ Nicole Isenhardt
Nicole Isenhardt
Paralegal

EXHIBIT 2

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**

Inv. No. 337-TA-1276

DECLARATION OF DR. RICHARD MILANI

1. My name is Dr. Richard Milani. I am over 21 years of age, of sound mind, and make this declaration voluntarily and based upon my own personal knowledge.

2. I received my M.D. from the University of Florida in 1979. I completed a residency in Internal Medicine at the University of Florida. I then completed fellowships in Critical Care Medicine at the University of Florida, Preventive Medicine and Clinical Epidemiology at Harvard University (Massachusetts General Hospital), and Cardiovascular Diseases at Ochsner Clinic Foundation.

3. I am the Chief Clinical Transformation Officer and Vice Chairman of the Department of Cardiology at Ochsner Health System (“Ochsner Health”). Ochsner Health is an integrated healthcare system with a mission to serve, heal, lead, educate, and innovate. It has more than 34,000 employees, and over 4,500 employed and affiliated physicians in over 90 medical specialties and subspecialties. Ochsner Health operates 40 hospitals and more than 300 health and urgent care centers across Louisiana, Mississippi and the Gulf South, and also serves many patients around the country and world through its digital medicine program. In 2021, Ochsner Health treated more than 1 million people from every state and 75 countries.

4. Since 2012, I have held the role of Chief Clinical Transformation Officer. My responsibilities include developing new methods of healthcare delivery that improve the health of the populations we serve, improve access to care, reduce the cost of care, and reduce the burden on the caregivers of care. To accomplish our goals, we take advantage of new leading edge capabilities that involve both technology as well as artificial intelligence.

5. I understand that Masimo has sued Apple for patent infringement, and that Masimo is seeking to exclude from importation into the United States several generations of Apple Watch that include the Irregular Rhythm Notification (“IRN”), electrocardiogram (“ECG”) App, High Heart Rate Notification (“HHRN”) and Blood Oxygen Sensor (SPO2) functionality.

6. As detailed below, excluding Apple Watch with these features would have major negative implications on public health in this country by greatly hindering patient care and/or medical research in critical areas.

7. The leading cause of death in the United States is chronic disease, ranging from diabetes, to heart disease, to high blood pressure, to Alzheimer's disease. More than 50% of adults in the United States have a chronic disease.¹

8. About 697,000 people died in the United States from heart disease in 2020; that's 1 in 5 deaths.² Heart disease costs the United states about \$229 billion each year.³

9. Atrial Fibrillation ("AFib") is the most common type of cardiac arrhythmia. It is often asymptomatic until a major health event occurs, such as a stroke. This is why it is highly valuable to a patient's care to have the ability to track a patient's heart rhythms continuously to check for abnormal rhythms and report such activity to a doctor before a patient experiences a life-threatening medical event such as a stroke. In 2019, AFib was mentioned in more than 183,000 death certificates, and was the underlying cause of death for at least 26,500 people in the United States.⁴

10. Historically, a key challenge for physicians when it comes to treating chronic disease has been a lack of timely and consistent data about the patient's health. Patients often are only seen by a physician a few times per year, and may also only have diagnostic testing associated with their chronic disease performed during those in-person visits. While these appointments and periodic testing provide a useful snapshot about a patient's health, they do not account for medical changes that may be occurring on a monthly, weekly, or daily basis. This applies to heart disease and AFib as well.

11. In 2014, Apple launched HealthKit. HealthKit is a HIPAA-compliant central repository of health and fitness data on Apple Watch. With a user's permission, apps can communicate with HealthKit to access and share this data. Since 2014, HealthKit has been integrated with Epic Systems, a leading provider of electronic medical records in the United States. This integration means that, with a patient's

¹ About Chronic Diseases | CDC *available at* <https://www.cdc.gov/chronicdisease/about/index.htm#:~:text=Chronic%20diseases%20such%20as%20heart,disability%20in%20the%20United%20States> .

² Heart Disease Facts | cdc.gov *available at* <https://www.cdc.gov/heartdisease/facts.htm#:~:text=Heart%20disease%20is%20the%20lead> .

³ *Id.*

⁴ https://www.cdc.gov/heartdisease/atrial_fibrillation.htm

permission, health data collected through Apple Watch can be transmitted directly to a patient's electronic medical record and accessible to their physician.

12. Since the launch of HealthKit, Apple has continued to expand the health features that its products track, while software developers have built apps to take advantage of this functionality. These advancements have major benefits when it comes to preventive care because they allow physicians to gather substantially more data about the health of their patients. They also allow physicians to more quickly detect changes in a patient's health, which can lead to earlier detection or deterioration of disease or illness, and can also provide an opportunity for physicians to help prevent catastrophic health events from occurring. This has benefits most importantly for patients, and also reduces the need for hospitalization further reducing healthcare costs. This has included collecting information from patients who have suffered episodes consistent with AFib. At Ochsner Health, we have built healthcare programs around HealthKit to take advantage of this Apple technology. This has led to substantial improvements in blood pressure and diabetes control for thousands of our patients, as well as earlier diagnosis of patients who have AFib from the IRN feature.

13. Indeed, recently, Apple announced a new feature that tracks AFib burden. Ochsner Health is building a management program around this Apple technology, called AFib History, which will give physicians weekly reports about the percentage of time a patient has spent in AFib (termed the "AFib burden") based on data collected from Apple Watch. We expect this to be a program that saves many lives, including by preventing strokes.

14. I am not aware of any comparable wearable product capable of tracking AFib burden. The standard way of monitoring patients with AFib today involves performing EKGs when necessary (which requires a trip to the doctor), sending patients home with a recording device (Holter monitor or single-lead ECG patch) that can be worn for short periods of time (i.e., 24 hours) to monitor and record cardiac activity, or implanting a medical device into a patient's chest through a medical procedure that will record cardiac activity. We expect that the ability to track a patient's cardiac activity daily, by simply having the patient wear an Apple Watch, will revolutionize the way we treat this disease and save many lives.

15. To date, Ochsner has invested approximately \$600,000 into building its AFib Management program. This involves a team of cardiologists, advanced practice providers, Epic software developers and engineers as well as app developers.

16. Another area where Apple's products have allowed for significant preventive medical advancements concerns falling. For those aged 65 and older, falling is a major health concern. Within this population, more than one in four people falls each year, and more than 3 million people are treated in emergency rooms for injuries related to their falls. In 2015, the total medical cost related to falls totaled more than \$50 billion.⁵

17. In 2021, Ochsner Health launched a pilot program related to fall prevention and management called "Connected Stability". This program relies on Apple Watch and iPhone, and has been a huge success among the approximately 350 patients who participated. The program uses fall detection on Apple Watch to detect when a patient falls. Specifically, Apple Watch can detect if a patient falls, and then offers users a chance to indicate through Apple Watch whether they are okay or if there is an emergency. If Apple Watch cannot detect any movement from the user within about one minute of the fall, it will automatically contact emergency services. In addition to this existing functionality, Ochsner has developed its own program through which a healthcare professional from Ochsner will contact a patient for whom Apple Watch has detected a fall to find out if they need any medical assistance (particularly for patients who have fallen but do not believe they need to go to the hospital).

18. For patients that have participated in the pilot program, we have been able to reduce falls by approximately 50%. We have also received incredible feedback from patients about the program. Patients report a tremendous improvement to their quality of life. They report that they are much less worried about falling, and also feel comfort in knowing that they will be able to receive medical assistance quickly if they do fall. We have also found that the 65 and older population is more inclined to wear an Apple Watch consistently than other types of personal emergency response systems (such as existing

⁵ <https://www.cdc.gov/falls/facts.html>.

products where the patient essentially wears an emergency button around their neck). This is because Apple Watch is relatively discrete and is a commonly used product, and it is something that they are not embarrassed to wear. Rather, they are excited to wear an Apple Watch and take advantage of its other functionality.

19. Ochsner has invested approximately \$3 million into its fall prevention pilot program. As mentioned above, more than 350 patients have participated so far. Ochsner plans to roll out this program nationally within the next year. Ochsner currently has more than 20 healthcare professionals working on this program, and we expect those numbers to grow significantly as the program expands.

20. Another feature that would be adversely impacted by the proposed exclusion order is the Apple Watch Blood Oxygen feature. Measuring a person's blood oxygen saturation is an important health and wellness metric, particularly in the midst of the COVID-19 pandemic. Taking this feature out of the hands of consumers would negatively impact the public health and welfare.

21. I am aware that recent medical literature and the FDA has raised concerns about racial bias in existing pulse oximeters. I understand that the disparity shown in the literature is, at least in part, attributed to dark pigments in certain users' skin. I understand that a white paper recently published by Apple identifies steps that Apple took to address this problem when designing the blood oxygen feature.⁶ I also understand that in a small-scale study involving the Apple Watch, there were no reported disparities in blood oxygen measurements between those with light and dark skin. Although these results are promising, I believe more research is needed to confirm the findings and assess whether Apple's blood oxygen sensor can take accurate measurements from persons of color.

22. As the above examples demonstrate, Apple is a leading innovator when it comes to healthcare technology. This technology is revolutionizing how we manage our patients. Preventing importation of Apple Watch would be devastating to the progress that is being made every day in this space.

⁶ https://www.apple.com/healthcare/docs/site/Blood_Oxygen_app_on_Apple_Watch_October_2022.pdf.

I declare, under penalty of perjury, under the laws of the United States of America, that the foregoing is true and correct.

Executed on March 1, 2023 in New Orleans, LA.

/s/ Dr. Richard Milani

Dr. Richard Milani

Chief Clinical Transformation Officer Ochsner
Health System

EXHIBIT 3



STEPHEN J. RUOSS, M.D

Professor of Medicine

Clinical Chief

Division of Pulmonary, Allergy and Critical Care Medicine

February 21, 2023

U.S. International Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

Re: Apple Watch with blood oxygen saturation monitoring feature

Members of the U.S. International Trade Commission,

I am writing to you as an academic pulmonary specialist physician as well as an elite athlete, in reference to the action before you regarding the Apple Watch with blood oxygen saturation monitoring feature. I am writing this letter to express my strong support for the blood oxygen saturation monitoring feature of the Apple Watch. I am not supported by Apple, Inc., and have no conflicts of interest regarding this subject or this letter to the Commission.

The oxygen saturation feature of the Apple Watch is a highly accurate device feature, with performance characteristics fully comparable to medical device standards for oximeters.

The oximetry feature of the Apple Watch is an important and very useful component of the physiology assessment capabilities of the Watch, which also include electrocardiogram (ECG) and irregular rhythm notification (IRN) features. These coupled assessment tools allow the Watch user to have a very sophisticated and useful composite view of their physiology, providing the benefit of highly accurate, important, and immediate information for their use.

One of the primary benefits of the blood oxygen monitoring feature is its ability to alert users to potential health issues. This feature can help users identify changes in their blood oxygen levels that may indicate a respiratory or cardiac problem, allowing them to seek medical attention promptly. Additionally, this feature may be particularly valuable for individuals who engage in high-altitude activities or suffer from sleep apnea, as it can help them monitor their oxygen levels and adjust their behavior accordingly.

Furthermore, I believe that the Apple Watch has a strong reputation for safety and effectiveness. Apple is a company that has demonstrated a commitment to user privacy and data security, which is especially important when it comes to health-related data. As a result, I have confidence that the blood oxygen monitoring feature on the Apple Watch is safe, accurate, and reliable.

In conclusion, as a pulmonary physician as well as an elite endurance athlete, I feel that the blood oxygen saturation monitoring feature of the Apple Watch is a highly valuable feature for Apple Watch users, and I strongly support retaining it as a component of the physiology monitoring capabilities of the Watch.

Sincerely,

A handwritten signature in blue ink, appearing to read "Stephen Ruoss".

Stephen Ruoss, MD

EXHIBIT 4



Russell Bowler, M.D. Ph.D.
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#1 or 2 respiratory hospital in the U.S.

US News & World Report

U.S. International Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

Re: Support for the Apple Watch for use in tracking physiologic features in medical patients.

Dear Members of the U.S. International Trade Commission:

I am writing to support Apple and their wearable device (Apple Watch). For the past 10 years I have conducted medical research studies involving wearable sensors that measure physiologic parameters (heart rate, physical activity, oxygen saturation, and temperature) in medical patients. We have published results in peer-reviewed medical journals (e.g., Bowler R, et al. *BMJ Open Resp Res* 2019;6:e000350. doi:10.1136/bmjresp-2018-000350) and presented our findings at scientific meetings (e.g., the American Thoracic Society). We have used both medical research devices (Actigraph) and consumer devices (Apple Watch, FitBit). A key feature of consumer devices is their integration of multiple sensors and particularly oxygen saturation (SpO2) for patients with respiratory diseases. In these patients from our research studies and personally my research group has found the Apple Watch to be an exceptional device that accurately measures important parameters such as heart rate, physical activity, and oxygen saturation. Coupled with monitoring apps, these parameters help predict the onset of acute illness. The devices are also significantly less expensive than research only devices and depriving consumers of the devices might unnecessarily limit access to remote medical monitoring in underserved groups (e.g., rural patients) who do not have ready access to specialists. I am happy to provide additional information to the Commission upon request. I do not have any conflict of interest other than many of these companies have provided these devices at substantial discount for research studies.

Sincerely,

A handwritten signature in black ink, appearing to read "Russell Bowler".

Russell Bowler, M.D., Ph.D.,
Director of COPD Clinic and Precision Medicine
Professor of Medicine
Division of Pulmonary Medicine, Department of Medicine
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EXHIBIT 5



Article

Assessment of Non-Invasive Measurements of Oxygen Saturation and Heart Rate with an Apple Smartwatch: Comparison with a Standard Pulse Oximeter

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† These authors contributed equally to this work.

Abstract: The most commonly used method to assess peripheral oxygen saturation (SpO₂) in clinical practice is pulse oximetry. The smartwatch Apple Watch 6 was developed with a new sensor and an app that allows taking on-demand readings of blood oxygen and background readings, day and night. The present study aimed to assess the feasibility and agreement of the Apple Watch 6 compared with a standard SpO₂ monitoring system to assess normal and pathological oxygen saturation. We recruited study participants with lung disease or cardiovascular disease and healthy subjects. A total of 265 subjects were screened for enrolment in this study. We observed a strong positive correlation between the smartwatch and the standard commercial device in the evaluation of SpO₂ measurements ($r = 0.89$, $p < 0.0001$) and HR measurements ($r = 0.98$, $p < 0.0001$). A very good concordance was found between SpO₂ (bias, -0.2289 ; SD, 1.66; lower limit, -3.49 ; and upper limit, 3.04) and HR (bias, -0.1052 ; SD, 2.93; lower limit, -5.84 ; and upper limit, 5.63) measured by the smartwatch in comparison with the standard commercial device using Bland–Altman analysis. We observed similar agreements and concordance even in the different subgroups. In conclusion, our study demonstrates that the wearable device used in the present study could be used to assess SpO₂ in patients with cardiovascular or lung diseases and in healthy subjects.

Keywords: Apple Watch 6; COVID-19; SpO₂



Citation: Spaccarotella, C.; Polimeni, A.; Mancuso, C.; Pelaia, G.; Esposito, G.; Indolfi, C. Assessment of Non-Invasive Measurements of Oxygen Saturation and Heart Rate with an Apple Smartwatch: Comparison with a Standard Pulse Oximeter. *J. Clin. Med.* **2022**, *11*, 1467. <https://doi.org/10.3390/jcm11061467>

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1. Introduction

The most widely used method to assess peripheral oxygen saturation (SpO₂) in clinical practice is pulse oximetry. The major advantage of this method is that it is non-invasive and has other benefits such as ease of use so that it can be used for multiple out-of-hospital measurements [1]. For these reasons, pulse oximetry is also often used in patients with COVID-19 to monitor peripheral oxygen saturation frequently [2]. Standard pulse oximetry measures the oxygen saturation in the blood by shining light at specific wavelengths through tissue. Deoxygenated and oxygenated hemoglobin absorb light at different wavelengths (660 nm and 940 nm, respectively), and an algorithm processes the absorbed light in the pulse oximeter to display a saturation value. The smartwatch Apple Watch 6 was developed with a new sensor and an app that allow taking on-demand readings of blood oxygen and background readings, day and night [3]. Smartwatches are widespread and are increasingly being used for digital health information. For instance, the Apple Watch can reliably detect atrial fibrillation [4–6], and we previously showed the possibility of

using this smartwatch to obtain multiple ECG leads [7] to detect ST-segment ECG changes. More recently, we and others demonstrated that it is possible to assess QTc measurements with the Apple Watch [8,9] and even Brugada syndrome ECG patterns [10]. Accordingly, the present study aimed to assess the feasibility and agreement of the Apple Watch 6 compared with a standard SpO₂ monitoring system to assess normal and pathological oxygen saturation in a large cohort of patients with cardiovascular disease, patients with lung disease and healthy subjects.

2. Materials and Methods

We recruited study participants older than 18 years with lung disease or cardiovascular disease. A group of healthy subjects was also included for comparison. Exclusion criteria were as follows: (1) missing upper extremity, hand, or finger; (2) inability to wear a watch because of wrist circumference or edema of the arm, wrist, or hand; (3) clinical instability.

The Ethical Committee of the University Magna Graecia approved the study, and all subjects included in this study gave their written informed consent. The study conforms to the principles outlined in the Declaration of Helsinki and is independent from industry.

Research staff were trained to measure SpO₂ and HR with a smartwatch and a standard pulse oximeter according to their manufacturers' guidelines. The SpO₂ and HR measurements were obtained with the Apple Watch 6 (Apple Inc., Cupertino, CA, USA) and with a standard Nellcor Portable SpO₂ Patient Monitoring System, PM10N (Medtronic, Minneapolis, MN, USA), placed on the index and middle fingers of the left hand (the same arm that was used for smartwatch measurement). The measurement accuracy of the latter system is ± 2 digits in the range of values from 70% to 100% for saturation, and ± 3 digits in the range of values from 20 to 250 bpm for pulse rate [11]. The measurements with the Apple Watch 6 and the Nellcor system were taken within 1 minute of each other in order to ensure comparability between the two devices. All subjects followed the same measurement schedule, and all measurements were repeated two times and averaged. Since movement artifacts are factors that can affect the reliability of measurements when using the smartwatch, particular attention was paid to its correct placement. During the measurements, the arms were placed at rest on a table. The wrist and palm were placed face down on a flat surface and held steady. Particular attention was paid to ensuring that the Apple Watch fitted snugly against the wrist. The wristband was snug but comfortable, and the back of the Apple Watch touched the wrist. If the wrist bones prevented the watch from fitting snugly, it was moved along the arm to about 2.5 to 5 cm above the wrist [12].

The primary aim of the study was the head-to-head comparison of the measurements of SpO₂ and HR by the smartwatch and the standard pulse oximeter. The secondary aim was the comparison of the measurements of SpO₂ and HR between subgroups (lung disease, CV disease, healthy subjects).

Continuous variables are presented as mean \pm standard deviation. For the assessment of differences in metric outcome variables, we used paired *t*-tests, and in the case of binary variables we used chi-square tests. A one-way analysis of variance (ANOVA) was used to determine any statistically significant differences between the means of two or more independent (unrelated) groups. A *p*-value of <0.05 was considered statistically significant. Shapiro–Wilk tests were used to assess the normality of continuous variables. The correlation between the two technologies was assessed using linear regression and estimated with Pearson analysis for normally distributed data and Spearman analysis for nonparametric data [13]. A plot of the differences between techniques was created according to the method described by J.M. Bland and D.G. Altman [14]. Statistical analyses were performed using MedCalc Statistical Software, version 14.8.1 (MedCalc Software, Ostend, Belgium), and GraphPad Prism, version 8.0.0 (GraphPad Software, San Diego, CA, USA).

3. Results

A total of 265 subjects were screened for enrolment in this study. Three subjects were excluded from the study as it was impossible to obtain data from them, probably due to them having small wrists. In five subjects, it was not possible to assess oxygen saturation with the Apple Watch despite multiple attempts, for reasons that could not be detected. After screening, 257 subjects were included in the present study. Of these 257 subjects, 56 were healthy controls, 60 were patients with lung disease, and 141 were patients with cardiovascular disease. The study population is described in Table 1.

Table 1. Participant characteristics.

	Healthy Subjects (<i>n</i> = 56)	Lung Disease (<i>n</i> = 60)	CV Disease (<i>n</i> = 141)	<i>p</i>
Age, <i>y</i> ± SD	43.18 ± 14.31	71.23 ± 10.44	69.21 ± 11.53	<0.001
Male, <i>n</i> (%)	24 (42.9)	45 (75)	99 (70.2)	<0.001
Weight, <i>n</i> ± SD	69.52 ± 12.15	77.59 ± 17.35	76.22 ± 15.08	<0.02
Height, <i>n</i> ± SD	168.30 ± 9.05	166.47 ± 7.37	165.51 ± 7.93	0.25
BMI, <i>n</i> ± SD	24.49 ± 3.64	27.90 ± 5.41	27.71 ± 4.50	<0.02
Hypertension, <i>n</i> (%)	10 (17.9)	52 (86.7)	126 (89.4)	<0.001
Diabetes mellitus, <i>n</i> (%)	4 (7.1)	21 (35)	47 (33.3)	<0.001
Dyslipidemia, <i>n</i> (%)	7 (12.5)	29 (48.3)	123 (87.2)	<0.001
ACS, <i>n</i> (%)	0 (0)	1 (1.7)	50 (35.5)	<0.001
CCS, <i>n</i> (%)	0 (0)	9 (15)	64 (45.4)	<0.001
Stroke/TIA, <i>n</i> (%)	0 (0)	3 (5)	6 (4.3)	<0.001
Smoke, <i>n</i> (%)	15 (26.8)	6 (10.0)	22 (15.6)	<0.001
COPD, <i>n</i> (%)	0 (0)	35 (58.3)	16 (11.3)	<0.001
OSAS, <i>n</i> (%)	0 (0)	16 (26.7)	10 (7.1)	<0.001
O ₂ therapy, <i>n</i> (%)	0 (0)	24 (40.0)	18 (12.8)	<0.001
Room temperature, <i>n</i> ± SD	21.79 ± 1.32	21.28 ± 0.55	21.32 ± 0.91	0.94
Body temperature, <i>n</i> ± SD	36.18 ± 0.36	36.20 ± 0.38	36.14 ± 0.40	0.98
Wrist circumference, <i>n</i> ± SD	16.15 ± 1.38	16.94 ± 1.15	17.03 ± 1.39	0.91

TIA = Transient Ischemic Attack; ACS = Acute Coronary Syndrome; CCS = Chronic Coronary Syndrome; BMI = Body Mass Index; OSAS = Obstructive Sleep Apnea Syndrome; COPD = Chronic Obstructive Pulmonary Disease.

Healthy subjects were younger than patients with lung or CV disease ($p < 0.001$) and had fewer risk factors. No differences were found regarding the technical features of measurements (room temperature, body temperature, wrist circumference; $p = \text{NS}$). We observed strong positive correlations between the smartwatch and the standard commercial device in the evaluation of SpO₂ measurements ($r = 0.89$, $p < 0.0001$) and HR measurements ($r = 0.98$, $p < 0.0001$) (Figure 1a,b).

A very good concordance was found between SpO₂ measured by the smartwatch in comparison with the standard commercial device (bias, -0.2289 ; SD, 1.66; lower limit, -3.49 ; and upper limit, 3.04) using Bland–Altman analysis. Figure 2a shows the difference in % of SpO₂ between the smartwatch and the standard commercial device plotted against the mean of the two readings. This difference was considered clinically nonsignificant. Similarly, an excellent agreement was found between HR measured by the smartwatch in comparison with the standard commercial device (bias, -0.1052 ; SD, 2.93; lower limit, -5.84 ; and upper limit, 5.63) using Bland–Altman analysis. Figure 2b shows the difference in beats per minute in HR between the smartwatch and the standard commercial device plotted against the mean of the two readings. This difference was considered clinically nonsignificant.

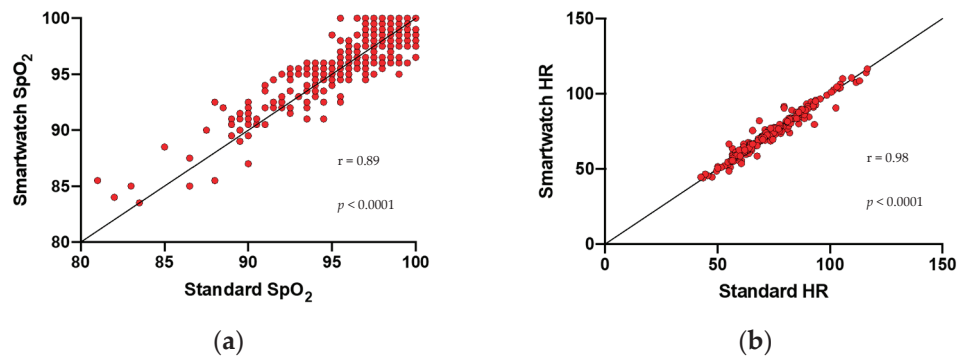


Figure 1. Correlation plots between the smartwatch and the standard commercial device. (a) Correlation between the smartwatch and the standard commercial device in the evaluation of SpO₂ measurements ($r = 0.89$). (b) Correlation between the smartwatch and the standard commercial device in the evaluation of HR measurements ($r = 0.98$).

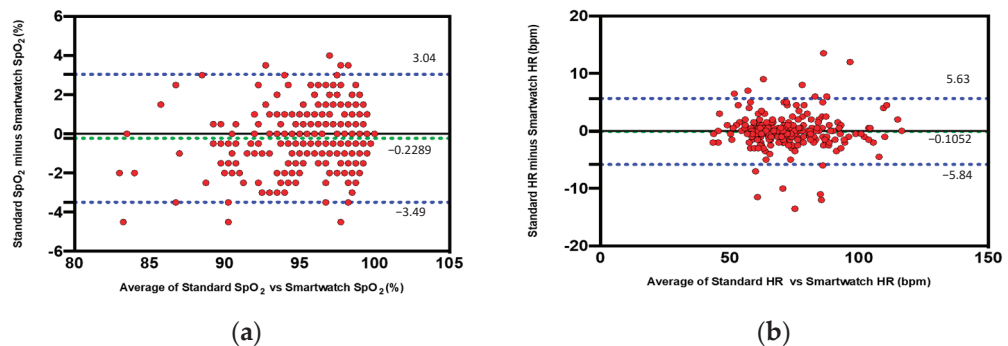


Figure 2. Concordance between SpO₂ and HR measured by the smartwatch in comparison with the standard commercial device using Bland–Altman analysis. Bland–Altman plots indicate the level of agreement between the smartwatch and the standard commercial device. The dashed green line represents the bias (mean difference), and the dashed blue lines represent the upper and the lower limits of agreement. This difference is considered clinically nonsignificant. (a) Difference in % of SpO₂ between the smartwatch and the standard commercial device plotted against the mean of the two readings. (b) Difference in beats per minute in HR between the smartwatch and the standard commercial device plotted against the mean of the two readings.

Furthermore, based on the mean differences between the smartwatch and the standard commercial device, no statistically significant differences were found in both SpO₂ and HR measurements ($p = 0.46$ and $p = 0.93$, respectively) (Figure 3a,b).

We observed similar agreements and concordance between the standard commercial device and the smartwatch even in the different subgroups (lung disease, cardiovascular disease) for both parameters, SpO₂ and HR (Figure S1).

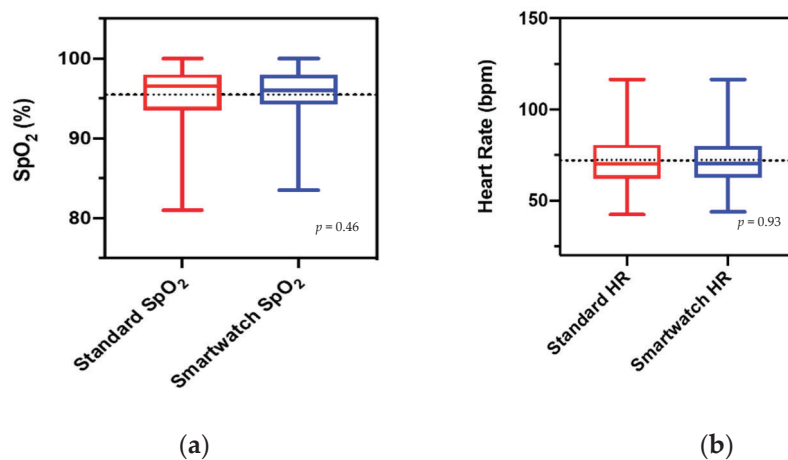


Figure 3. Boxplots of the mean differences between the smartwatch and the standard commercial device. (a) Mean difference in SpO₂ between the smartwatch and the standard commercial device ($p = 0.46$) (b) Mean difference in HR between the smartwatch and the standard commercial device. ($p = 0.93$).

4. Discussion

The major result of the present study is that the measurements of SpO₂ obtained using the Apple Watch are reliable compared to the standard pulse oximetry technique in patients with cardiovascular disease, lung disease, and healthy subjects. It has been estimated that the number of Apple Watches in use worldwide is about 100 million [15]. These smartwatches are used today in cardiology, especially for the accurate and reliable diagnosis of atrial fibrillation [4–6]. Furthermore, the possibility of measuring changes in the ST segment has recently been demonstrated in our laboratory for the first time [7]. In this study, the watch was placed in different body positions to obtain nine bipolar ECG tracings (corresponding to Einthoven leads I, II, and III). The multichannel smartwatch ECG reliably identified ST-segment changes in patients with acute coronary syndromes (NSTEMI and STEMI). Finally, we and others demonstrated that the smartwatches could be used in measuring the QT interval [8,9] and even Brugada syndrome [10]. As an additional feature, Apple developed the smartwatch Apple Watch 6 (Apple Inc, Cupertino, CA, USA) with a new sensor that consists of four LED clusters and four photodiodes. Incorporated into a completely redesigned crystal, this new sensor works in concert with the blood oxygen app to determine blood oxygen levels. Green, red, and infrared LEDs shine light onto the blood vessels in the wrist, and photodiodes measure the amount of light reflected. A recent study by Pipek et al. in outpatients with chronic obstructive pulmonary disease or interstitial lung diseases observed positive correlations between the Apple Watch device and commercial oximeters when evaluating heart rate measurements ($r = 0.995$, $p < 0.001$) and oximetry measurements ($r = 0.81$, $p < 0.001$) [16]. Our study is larger and improves on prior studies on this topic by including patients with cardiovascular disease. However, in contrast with the study by Pipek et al. [16], our study did not demonstrate differences in mean values of SpO₂ measured with the Apple Watch compared to standard oximeters (Figure 3a). Therefore, our data did not show higher values with the Apple Watch compared to standard oximeters. Our data demonstrated a very good concordance between the SpO₂ measured by the smartwatch compared with the standard commercial device (bias, -0.2289 ; SD, 1.66; lower limit, -3.49 ; and upper limit, 3.04). Therefore, the continuous monitoring of blood oxygen saturation with the wearable device assessed in the present study can be beneficial in various settings, both in patients with cardiovascular or lung diseases and in healthy subjects.

There are several limitations of the present report. In our study, even under ideal conditions, in a small percentage of cases (eight subjects) it was not possible to measure oxygen levels with the smartwatch. Skin perfusion, the anatomical variability of the wrist,

and other reasons could be responsible. The data from our study were acquired in a well-controlled environment with a constant room temperature (20 ± 2 °C). Therefore, these results might not apply to different temperatures and environments—for example, in cold or hot temperatures. Another significant limitation is the lack of laboratory data as well as the fact that there were few subjects with saturation $< 90\%$ or with heart rate $> 100/\text{min}$. The Apple Watch was used by an expert medical operator and the data accuracy might not apply to a broad population of users. Permanent or temporary changes to the skin, such as some tattoos, are another factor that can affect measurements. The ink used in some tattoos, as well as their design and saturation, can block light from the sensor, preventing the O₂ levels app from taking measurements. The accuracy of pulse oximetry can be influenced by multiple factors, including perfusion and skin pigmentation [17]. In our population, however, all subjects were white and without tattoos in the skin area used for smartwatch use.

5. Conclusions

In conclusion, our study demonstrates that the wearable device used in the present study could be used to assess SpO₂ in patients with cardiovascular or lung diseases and in healthy subjects.

Supplementary Materials: The following supporting information can be downloaded at: <https://www.mdpi.com/article/10.3390/jcm11061467/s1>, Figure S1. Agreements and concordance between the standard commercial device and the smartwatch in the different subgroups. Table S1. SpO₂ Correlation between the smartwatch and the standard commercial device in different subgroups. Table S2. SpO₂ Concordance between the smartwatch and the standard commercial device in difference subgroups. Table S3. HR Correlation between the smartwatch and the standard commercial device in different subgroups. Table S4. HR Concordance between the smartwatch and the standard commercial device in difference subgroups.

Author Contributions: Conceptualization, C.S. and C.I.; methodology, A.P.; software, A.P.; validation, C.S.; formal analysis, A.P.; investigation, C.M. and C.S.; resources, C.I.; data curation, C.M.; writing—original draft preparation, A.P.; writing—review and editing, C.M. and C.I.; visualization, A.P.; supervision, G.E., G.P. and C.I.; project administration, C.I. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethical Committee of the University Magna Graecia.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data underlying this article will be shared upon reasonable request to the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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EXHIBIT 6

Commercial smartwatch with pulse oximeter detects short-time hypoxemia as well as standard medical-grade device: Validation study

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Abstract

Objective: We investigated how a commercially available smartwatch that measures peripheral blood oxygen saturation (SpO₂) can detect hypoxemia compared to a medical-grade pulse oximeter.

Methods: We recruited 24 healthy participants. Each participant wore a smartwatch (Apple Watch Series 6) on the left wrist and a pulse oximeter sensor (Masimo Radical-7) on the left middle finger. The participants breathed via a breathing circuit with a three-way non-rebreathing valve in three phases. First, in the 2-minute initial stabilization phase, the participants inhaled the ambient air. Then in the 5-minute desaturation phase, the participants breathed the oxygen-reduced gas mixture (12% O₂), which temporarily reduced their blood oxygen saturation. In the final stabilization phase, the participants inhaled the ambient air again until SpO₂ returned to normal values. Measurements of SpO₂ were taken from the smartwatch and the pulse oximeter simultaneously in 30-s intervals.

Results: There were 642 individual pairs of SpO₂ measurements. The bias in SpO₂ between the smartwatch and the oximeter was 0.0% for all the data points. The bias for SpO₂ less than 90% was 1.2%. The differences in individual measurements between the smartwatch and oximeter within 6% SpO₂ can be expected for SpO₂ readings 90%–100% and up to 8% for SpO₂ readings less than 90%.

Conclusions: Apple Watch Series 6 can reliably detect states of reduced blood oxygen saturation with SpO₂ below 90% when compared to a medical-grade pulse oximeter. The technology used in this smartwatch is sufficiently advanced for the indicative measurement of SpO₂ outside the clinic.

Trial Registration: ClinicalTrials.gov NCT04780724

Keywords

Wearables, oxygen saturation, pulse oximetry, reflectance mode, hypoxemia, hypoxic gas mixture, Apple Watch

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Introduction

Recently, consumer wearables have created the vision of new possibilities for personal care.^{1–5} Routine monitoring of biological signals such as heart rate or sleep pattern using wearable devices is an emerging trend in health monitoring outside the clinic and in-home care with a multi-billion dollar potential.^{6,7} The COVID-19 pandemic and its aftermath will only emphasize this trend.^{8,9} Nevertheless, the clinical applicability of wearables must be separated from consumer curiosity.^{10–14} Currently, the role of smartwatches in health care is investigated and discussed.

Earlier feasibility studies focused on activity monitoring and

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chronic disease self-management.^{15,16} Recent prospective studies have looked at the use of smartwatch technology in a range of medical applications such as the detection of atrial fibrillation,^{17,18} sleep monitoring,¹⁹ post-admission recovery in pediatric patients with respiratory diseases,²⁰ monitoring women during pregnancy²¹ or pre-habilitation prior to abdominal cancer surgery.²² Several studies were also interested in using smartwatch data in the detection of viral infections such as COVID-19.^{23,24} However, a previous study warned that a smartwatch did not have sufficient accuracy in measuring blood pressure or pulse oximetry compared to clinical standards.¹³

Pulse oximetry as a method of indirect measurement of peripheral blood oxygen saturation (SpO₂) is a relatively new metric in smartwatches, but it is becoming routinely available in new models,²⁵ allowing convenient SpO₂ monitoring at home or, with some restrictions due to movement, outdoors without the need for a dedicated pulse oximeter. In addition, the smartwatch's SpO₂ sensor does not need to be attached to a finger to complicate daily activities. This might be useful not only to athletes in training or mountaineers in high altitudes but more importantly to patients suffering from cardiovascular diseases, lung diseases such as chronic obstructive pulmonary disease (COPD), or dealing with the consequences or concerns of COVID-19.^{26,27} In particular, the ability of smartwatches to measure SpO₂ without conscious user intervention might help to detect intermittent hypoxemia associated with sleep apnea, a chronic health disorder that results in neurocognitive dysfunction and cardiovascular problems.^{28–30}

Pulse oximetry is an optical method that evaluates changes in light absorption at multiple frequencies due to the oxygen content in arterial blood. Levels of SpO₂ 95% or higher are considered normal, whereas SpO₂ below 90%, even if transient, is considered clinically relevant.³¹ Standard medical pulse oximeters, including portable oximeters, use transmission pulse oximetry, in which the light sources and the photodetector are positioned on the opposite sides of the measurement site (usually a thin place such as a fingertip or an earlobe) and the light passing through the site is evaluated. Smartwatches, and other wrist-worn devices, for practical reasons, utilize reflectance pulse oximetry, in which the light sources and the photodetector are positioned on the same side of the measurement site and the light reflected into the photodetector from the tissue is evaluated. Reflectance pulse oximeters face less light absorption and thus have less power consumption, can be placed at diverse measurement locations, and the absence of moving parts increases their resistance to motion artifacts.^{32,33} However, in practice, the reflectance mode can exhibit a low signal-to-noise ratio and be sensitive to ambient light sources.³⁴ At the wrist, the performance of the reflectance pulse oximeter depends on the exact placement of the sensor.^{34,35} In a study with an experimental reflectance pulse oximeter system, SpO₂ measurement at the wrist showed an unacceptably large

error.³⁶ Similarly, a study with a wrist-worn reflectance pulse oximeter under development found its performance was worse than finger-based oximeters and it was not able to detect hypoxemia.³⁷ Also, Hermand et al. reported a commercial smartwatch failed to provide trustworthy SpO₂ values, especially during induced oxygen desaturation.³⁸ On the other hand, a study by Lauterbach et al. tested a commercial smartwatch in a normobaric hypoxia chamber and found only minimal differences in SpO₂ measured by the smartwatch compared to a standard pulse oximeter,²⁶ with the largest difference for the lowest inspiratory oxygen fraction. Other recent studies have also reported positive results on the accuracy of wrist SpO₂ measurements by commercial devices, but most of them did not focus on hypoxia.^{39–42}

Thus, there are currently a few studies available that evaluate wrist SpO₂ measurement with mixed results. Concerns about measurement accuracy remain and, as new smartwatch models are launched, further studies are desirable.²⁷ A question persists whether wrist-worn devices, and smartwatches in particular, can monitor SpO₂ even in low blood oxygen levels well enough to provide early warning of desaturation episodes.

This study aims to compare the measurement of peripheral blood oxygen saturation using a very popular smartwatch to a medical-grade pulse oximeter at normal and potentially hypoxic levels.

Methods

The prospective single-arm interventional study was approved by the Ethical Review Board of the Faculty of Biomedical Engineering, Czech Technical University in Prague (No. B1/2021). The study was registered with ClinicalTrials.gov (identifier NCT04780724).

Recruitment

Twenty-four healthy student volunteers (mean \pm SD: age 24 \pm 2 years, height 181 \pm 8 cm, mass 77 \pm 11 kg) were recruited for the study. They were only included if they did not suffer from any disease of the cardiovascular system and had no injury to the upper limbs or hands that could affect the peripheral perfusion. In addition, participants were excluded for pregnancy, diabetes, hypotension, hypertension, acute asthma or any other acute respiratory disease. None of the participants used nail polish or had false nails at the time of the measurement. Participants were required to stay at least 30 min at rest before entering the laboratory. All participants provided written informed consent before their enrollment into the study.

Experiment setup and protocol

Upon arrival at the laboratory, Apple Watch Series 6 (Apple Inc., Cupertino, CA, USA)—further referred to as the smartwatch—was placed on a participant's left wrist and

the sensor of a medical-grade pulse oximeter Radical-7 (Masimo Corp., Irvine, CA, USA)—further referred to as the oximeter—was attached to the left middle finger of the participant. During the experimental procedure, SpO₂ readings were taken by hand from the smartwatch and oximeter simultaneously. Participants were sitting at rest throughout the experiment, and they were asked to keep their hands still on the table with their wrist and palm down and flat and avoid any movement according to the instructions of the smartwatch manufacturer.

A simple breathing circuit with a three-way non-rebreathing valve was assembled for the experiment. It allowed the participant to inhale the hypoxic gas mixture (12% O₂) from a polyethylene Douglas bag or the ambient air and to exhale into the ambient air outside the Douglas bag. The gas composition was monitored continuously by a Datex Ohmeda S/5 patient monitor (Datex-Ohmeda Inc., Madison, WI, USA) with a sensor placed between the three-way valve and the participant. A disposable antibacterial filter separated the participant from the breathing circuit.

There were three phases of the experimental procedure. During the first 2 min, in the initial stabilization phase, participants inhaled the ambient air via the breathing circuit. Two SpO₂ readings were taken (times 0:45 min and 1:15 min of the experiment). Then, in the 5-minute desaturation phase, participants inhaled the hypoxic gas mixture from the Douglas bag. Readings of SpO₂ were taken every 30 s (from time 2:45 min to time 6:45 min of the experiment). The final stabilization phase followed when the participants inhaled the ambient air and SpO₂ was recorded every 30 s (from time 7:30 min) until SpO₂ returned to normal values. Typically, three or four readings were taken in the final stabilization phase. Each participant underwent the experimental procedure twice. There was a delay of a minimum of 1 h between the two iterations of the experimental procedure to address possible slow washout of test gas.

Data processing and analysis

We concluded that the number of participants enrolled in the study and the number of paired SpO₂ observations would meet the basic recommendations of the Food and Drug Administration and the International Organization for Standardization (ISO 80601-2-61) for study design for in vivo accuracy testing of pulse oximeters (10 or more healthy subjects, 200 or more paired measurements).^{43,44}

We used the Bland–Altman analysis to compare the agreement between simultaneous smartwatch and oximeter SpO₂ measurements. The Bland–Altman analysis looks at two parameters, the bias and 95% limits of agreement. The bias is quantified as the mean difference in the paired measurements. The 95% limits of agreement, calculated as the mean difference \pm 1.96 standard deviations, determine the range of expected difference in future

simultaneous smartwatch and oximeter measurements. Uncertainties in the estimates of the bias and 95% limits of agreement are expressed as 95% confidence intervals. The standard deviation was calculated using the modified Bland–Altman method for multiple observations per individual when the measured quantity changes over the period of observation.⁴⁵ In addition, we evaluated the root mean square difference between smartwatch and oximeter paired measurements as

$$A_{\text{rms}} = \sqrt{\frac{\sum (\text{SpO}_{2,\text{smartwatch}} - \text{SpO}_{2,\text{oximeter}})^2}{n}}$$

where n is the number of evaluated pairs of SpO₂ measurements.⁴⁴

Further, the differences in the smartwatch and oximeter measurements were evaluated with respect to study time, that is, to evaluate the relative response rate of the two devices. To do this we averaged the measurements of all participants at each study time for the smartwatch and for the oximeter. The mean SpO₂ values across all participants and iterations of the experimental procedure were used to graphically compare the average time courses of the pooled smartwatch data and the pooled oximeter data. A two-tailed paired t test was used to evaluate the statistical difference between the smartwatch data and the oximeter data at each measurement time. P value less than 0.05 was considered statistically significant. Only the observations, where simultaneous readings from both devices were available, were included in the analysis. All data were analyzed in Matlab 2021a (MathWorks, Natick, MA, USA) after transcription from the log.

Results

Agreement between devices

The study was conducted in the Laboratory of special equipment for ICU of the Czech Technical University in Prague, Department of Biomedical Engineering, Kladno, Czech Republic, during February and March 2021 at an altitude of 405 m (1330 ft). All 24 volunteers (five women and nineteen men, all Caucasian, aged 20–28 years) completed the experiment with two iterations of the experimental procedure and two measuring devices, so there were 48 series of paired measurements available. As in some cases, one of the devices did not provide a valid reading, there were 1284 valid paired readings in total out of a possible number of 1364. The SpO₂ readings ranged between 76% and 100%. Most (75%) were between 90% and 100%, 24% between 80% and 89% and 1% below 80%.

The presented Bland–Altman plot is based on 642 individual data points calculated from all complete pairs of pooled SpO₂ readings (Figure 1). The bias (mean

difference) in SpO_2 between the smartwatch and oximeter was 0.0% for all the data points. The 95% confidence limits of the bias were -0.2% and 0.3% , indicating that there was no statistically significant bias between the measuring devices. The 95% limits of agreement were estimated to be -5.8% and 5.9% . The most extreme individual differences between the smartwatch and oximeter SpO_2 measurements were -9% and 17% . The A_{rms} evaluated across the pooled SpO_2 readings was 3.0% . The same approach was used to analyze the data after splitting into SpO_2 90%–100% and SpO_2 less than 90%. The results are summarized in Table 1. As shown, the absolute bias was greater for SpO_2 measurements under 90%.

Average response of devices

The time series of average smartwatch and oximeter measurements show the absolute differences between the means of SpO_2 measurements were small (Figure 2). The difference between the means of the smartwatch and oximeter ranged from -0.64% (study time 195 s) to 0.74% (study time 480 s) with the minimum absolute difference of the means 0.22% (study time 450 s). None of the differences between paired smartwatch and oximeter measurements at any study time reached a statistically significant difference.

Discussion

Principal results

The main finding of our study is that SpO_2 measurement by Apple Watch Series 6, a consumer product, did not differ on average from SpO_2 measurement by Masimo Radical-7 pulse oximeter, a medical device. The average absolute difference or bias between smartwatch and oximeter SpO_2 measurements, evaluated for all pooled data, in two ranges and at the individual study times, was less than 1% SpO_2 . This is the resolution in which the SpO_2 values are displayed on both devices.

At low-oxygen levels, the smartwatch tended to measure higher SpO_2 values than the oximeter, and this difference averaged approximately 1% SpO_2 for readings less than 90%. The time chart (Figure 2) illustrates a very similar response of both devices for the “average patient,” with the average difference between SpO_2 reported by the smartwatch and oximeter at the end of the desaturation phase being only 0.26% , and -0.23% upon recovery. The time series in Figure 2 also suggests that the response of the smartwatch to sudden desaturation may be slower than the response of the oximeter. The smartwatch required a 15-s period for a single SpO_2 measurement compared to the 2–4-s averaging time of the oximeter, so the smartwatch reading lagged behind the oximeter readings during the continuous SpO_2 decrease. This may have contributed to

the higher average SpO_2 measured by the smartwatch during induced desaturation. Generally, there are differences between the reaction times of pulse oximeters to sudden hypoxia.⁴⁶ During the experiments, we also observed a faster return of smartwatch values than oximeter in the final stabilization phase after the desaturation phase, but not being the primary concern of our study, there were not enough data to evaluate for this.

Comparison with prior work

Several studies have evaluated smartwatches in hypoxemia. In their analysis, Lauterbach et al. compared a different smartwatch Garmin fēnix® 5X Plus (Garmin, Olathe, KS, USA) with a medical-grade pulse oximeter Model 7500 (Nonin Medical BV, Amsterdam, the Netherlands) in a customized chamber that allowed to change and maintain the inspiratory oxygen fraction. Twenty-three volunteers breathed a gas mixture under normobaric conditions with inspiratory oxygen fractions between 14% and 21%. The study reported SpO_2 bias (smartwatch–oximeter) only 0.7% – 0.8% for higher values of the inspiratory oxygen fraction, but 3% for the smallest inspiratory oxygen fraction. Two explanations were offered for the bias increase by the authors of the study; first, elevated PaCO_2 levels resulting in increased other hemoglobin derivatives in the bloodstream, and second, hypoxia-mediated vasoconstriction that altered blood flow in fingers compared to the wrist.²⁶ Hermand et al. compared a smartwatch from the same manufacturer (Garmin Forerunner 245) with a medical-grade oximeter on 10 healthy participants during normoxia and normobaric hypoxia when the inspiratory oxygen fraction was gradually reduced to 10.5%. The total observed bias of the smartwatch was 5.4%, and the bias for the lowest oxygen fraction was even 13.2%. The authors concluded the smartwatch was not a reliable alternative to medical-grade oximeters.³⁸ A study with another smartwatch (Withings ScanWatch) by Kirszenblat and Edouard reached opposite findings. Measurements of SpO_2 in 14 healthy participants were compared with arterial blood oxygen saturation (SaO_2) determined with a co-oximeter at various stable levels of oxygen saturation. The total bias found was 0.98% (right wrist) and 1.56% (left wrist), and overall accuracy was adequate to medical-grade oximeters.⁴⁰ Our results, i.e., the negligible bias at higher saturation and the small bias with decreased saturation, generally correspond to those of Lauterbach et al. and Kirszenblat and Edouard although we detected a smaller bias for lower inspiratory oxygen fraction (12% in our study vs. 14%) and somewhat lower measured SpO_2 values than Lauterbach et al. We also suggest that the differences reflect different devices used in the studies.

Two recent studies examined the SpO_2 measurement using Apple Watch Series 6 compared to medical-grade pulse oximeters.^{41,42} The studies on subjects at rest

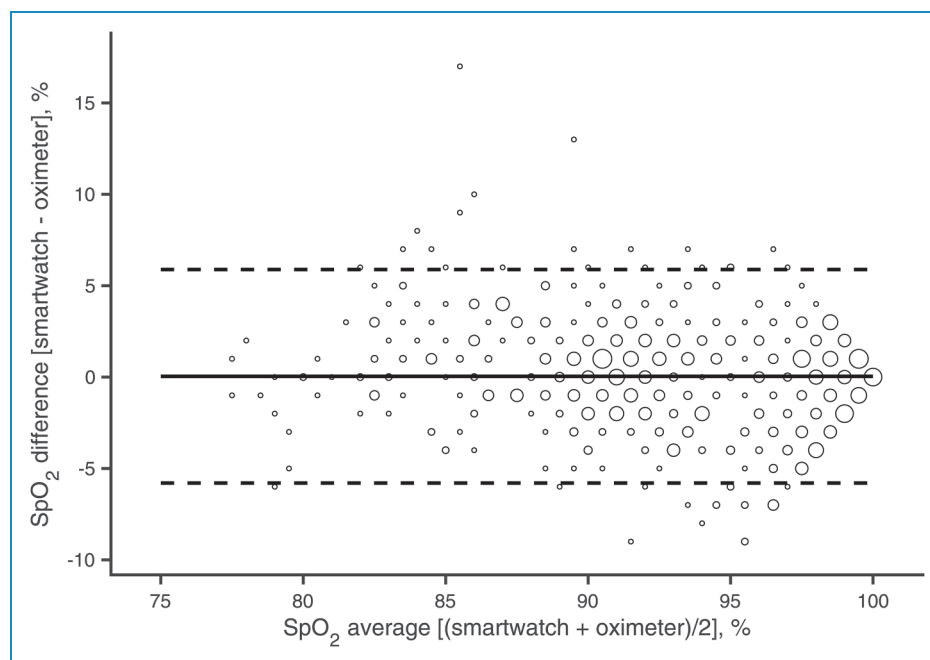


Figure 1. Differences between simultaneous SpO₂ readings of the smartwatch (Apple Watch 6) and oximeter (Masimo Radical-7) across different ranges of oxyhemoglobin saturation. Pooled SpO₂ measurements were analyzed for all participants grouped. The solid line is the mean difference of the measurements (bias). Dashed lines are the 95% limits of agreement. The area of markers is proportional to the number of measurements.

Table 1. Comparison of measurement bias and agreement.

SpO ₂ ^a , %	Bias ^b (95% CI), %	Lower LOA (95% CI), %	Upper LOA (95% CI), %	A _{rms} , %
Entire range	0.0 (−0.2 to 0.3)	−5.8 (−6.2 to −5.4)	5.9 (5.5–6.3)	3.0
<90	1.2 (0.7 to 1.7)	−5.3 (−6.1 to −4.4)	7.6 (6.7–8.4)	3.4
90–100	−0.3 (−0.6 to 0.1)	−5.8 (−6.2 to −5.4)	5.1 (4.7–5.5)	2.8

^a[(smartwatch + oximeter)/2].

^b[smartwatch − oximeter].

LOA: 95% limits of agreement.

included both healthy participants and diseased participants with lung or cardiovascular diseases. Both studies reported a bias (smartwatch–oximeter) of less than 1% and no significant differences between subject groups (healthy or diseased). However, neither of the two studies induced hypoxemia in the subjects, and they contained very few SpO₂ measurements below 90%.

The differences between Apple Watch Series 6 and Masimo Radical-7 within 6% SpO₂ can be expected for individual measurements for SpO₂ readings 90%–100% and up to 8% for SpO₂ readings less than 90%. This again is consistent with Lauterbach et al. and Kirszenblat and Edouard who reported 95% limits of the agreement up to 8.6% and 6.6%, respectively. The differences in individual SpO₂ measurements between the smartwatch and oximeter are also similar to what was reported as

differences in individual SpO₂ measurements against direct measurements of SaO₂ by co-oximetry under progressive normobaric hypoxia. The 95% limits of agreement reported by Kolb et al. were (−6.5%, 5.6%) and (−7.6%, 9.8%) for SpO₂ finger measurements when SaO₂ was above 85% and under 85%, respectively.⁴⁷ Others also reported individual readings may differ as much as 6%.⁴⁸ In a more recent study, narrower 95% limits of agreement (−1.8%, 1.8%) were reported by Louie et al. for a nonmotion SpO₂ measurement when SaO₂ was above 90%.⁴⁹

The root mean square difference is the standard metric for assessing accuracy in pulse oximetry that combines bias and precision of the SpO₂ measurement when compared to co-oximetry. Accuracy better or equal to 4.0% SpO₂ is required in general.⁴⁴ Typically, A_{rms} ≤ 3.0 and A_{rms} ≤ 3.5 are expected for transmittance and reflectance

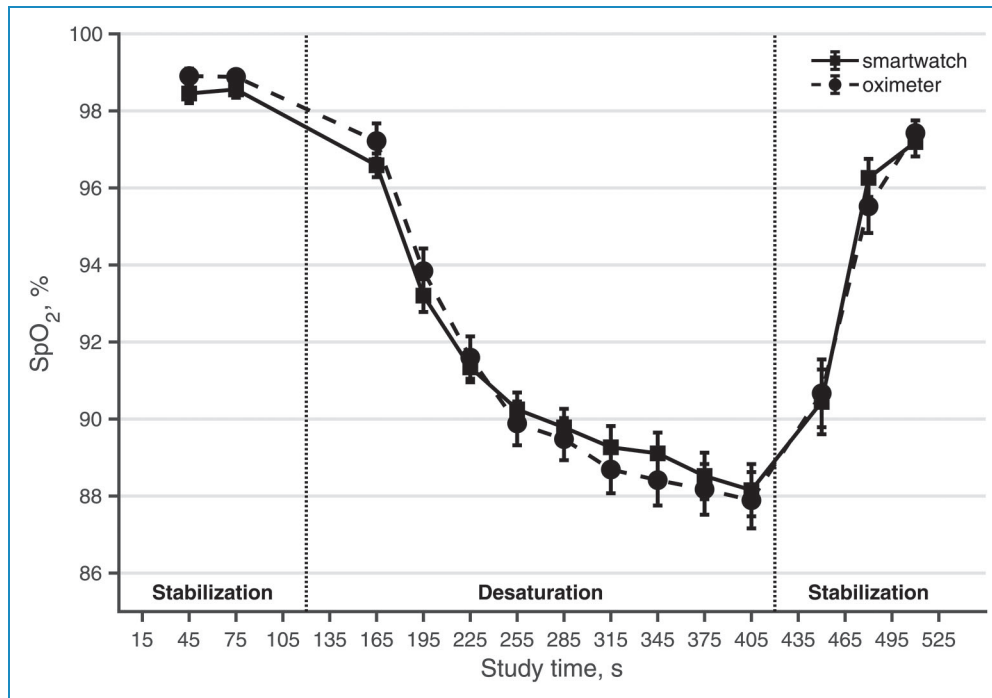


Figure 2. The time courses of the mean of all smartwatch SpO₂ measurements (Apple Watch 6) and the mean of all oximeter SpO₂ measurements (Masimo Radical-7) across all 24 participants. Data are mean \pm SEM.

sensors, respectively.⁴³ Medical-grade oximeters have an accuracy of 2%–3% according to manufacturers or 3%–4% according to what was reported in clinical studies.^{32,50} Numerous studies however reported that the accuracy of pulse oximeters deteriorates as blood oxygen saturation decreases.^{47,49,51,52} The A_{rms} metric has also been utilized when comparing SpO₂ measurements. Verkruysse et al. compared contactless photoplethysmography with a median of measurements taken by standard pulse oximeters in healthy adults under normoxic conditions and also hypoxic conditions where the inspiratory oxygen fraction was about 15%.⁵³ They estimated $A_{rms} \leq 2.5\%$ for short-time segments and even $A_{rms} \leq 1.7\%$ when discarding short-time errors. Hahnen and her colleagues investigated the accuracy of a handheld portable device for vital sign measurements on 85 participants and reported A_{rms} was 3.1% for SpO₂ when compared to a medical-grade vital signs monitor.¹³ In this context our results, $A_{rms} < 3.0\%$ for saturation of 90% and greater and $A_{rms} < 3.5\%$ for saturation under 90%, seem within the expected range with some of the 6%–8% span likely attributable to the Masimo device. Even with the large uncertainty between paired measurements, the smartwatch seems reliable in detecting relevant drops in SpO₂ below 90% even of short duration.

Limitations

Our study has numerous limitations. The study included only healthy young volunteers and short-time desaturation induced by the low-oxygen level of the inhaled gas

mixture. The results could be different in the case of chronic elderly patients with very long or extreme desaturations. However, the contribution of wearables for such patients in real-world situations will not be a detailed analysis of the severity of the condition, but rather a warning of an aggravated trend in the chronic problem or a sudden major change. Our results suggest that SpO₂ monitoring using wearables could be, due to its ability to detect the magnitude and speed of desaturation, a useful tool in self-care outside the clinic.

We did not evaluate SaO₂ in our study as this would require arterial blood sampling and greatly complicate the experiment. It was demonstrated that SpO₂ overestimates saturation compared to SaO₂.^{52,54,55} Due to the inaccessibility of actual SaO₂ values, we chose 12% O₂ and the 5-minute duration of the desaturation phase as the limit to avoid a frequent decrease of SpO₂ below 80% and prevent transient cognitive effects that may be associated with deep hypoxia.⁵⁶ The reduced oxygen fraction we used under normobaric conditions corresponds approximately to the partial pressure of oxygen at an altitude of 4400 m and the results of our study may therefore not be applicable to areas of higher altitude or to SpO₂ below 80% in general.

The steady decline of the SpO₂ levels at the end of the desaturation phase (Figure 2) suggests that the desaturation phase needed to be extended to reach the plateau. This may have better explained whether there was some time delay in the smartwatch readings compared to the oximeter

readings. Nevertheless, our focus was primarily on whether the smartwatch can provide an alert of the same quality as repeated SpO₂ measurements with a medical-grade pulse oximeter and thus be a useful screening method for detecting hypoxia.

Finally, in our study, we used one type of smartwatch from a single manufacturer. This must be considered when generalizing our observations to other smartwatches in the rapidly evolving market. Smartwatches from other manufacturers may show differences in performance, even if they use the same principle of reflectance pulse oximetry, as several hardware and software factors can affect the PPG signal, including the geometry of the light emitter and light detector or denoising.⁵⁷ Smartwatch performance may also vary between users at rest and while active. We measured participants at rest, as required by the manufacturer. The results may not correspond to measurements during or just after sporting activities due to motion artifacts, which could be the subject of further study.

Future perspectives

The availability and convenience of measuring biological signals using wearable devices such as smartwatches offer the potential to expand patient care options in chronic disease management. The clinical standard so far has been isolated measurements under the supervision of health professionals, which are taken with a relatively large time lag and then compared with the prevalence of the clinically relevant events in the population. Wearables allow long-term and continuous monitoring of trends or, on the contrary, detection of abnormal fluctuations in individuals^{9,11,58} and thus more quickly assess the change in their health status over time. Wearables are not intended to replace medical devices, but they need sufficient accuracy to provide an approximate assessment of an individual's condition.⁵⁹ The risk is both overreacting to clinically irrelevant fluctuations in monitored signals and neglecting serious changes related to real health complications.¹⁴ In particular, while portable pulse oximeters with transmission technology have been shown to be comparable to patient monitors,⁶⁰ data contradict SpO₂ measurement with commercial smartwatches as this feature is relatively new. The results of our study are intended to help fill this gap. They suggest that smartwatch technology for measuring SpO₂ has matured enough to be considered part of patient care. This can help detect hidden, but potentially serious problems such as sleep apnea, which is a growing problem with possible cognitive impacts,⁵⁶ or in the early detection of acute exacerbations of chronic conditions such as COPD.¹⁴ We further suggest that the exact requirement of each of these potential health care applications need to be articulated and wearable devices evaluated against those requirements.

Conclusions

Apple Watch Series 6, as a representative of wearables, provides reliable SpO₂ values as compared to a medical-grade pulse oximeter, at both normal oxygen levels and induced desaturation with SpO₂ below 90%. The SpO₂ monitoring technology used in this smartwatch is sufficiently advanced for the indicative measurement of SpO₂ outside the clinic and can detect states of reduced blood oxygen saturation.

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EXHIBIT 7

EXHIBIT 8

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**In the Matter of
CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**RESPONDENT APPLE INC.'S PETITION FOR REVIEW OF
THE INITIAL DETERMINATION OF VIOLATION OF SECTION 337**

device in which it is mounted, to incorporate ergonomic features that allow for good optical coupling with the tissue being measured, or for other technical or stylistic reasons.” RX-0411 at 7:58-63. Lumidigm also discloses that its sensor can be incorporated into a “portable electronic device,” along with other standard components such as processors, memory, and wireless communication interfaces, and provides as examples user-worn wristwatches, key fobs, cell phones, and personal digital assistants. RX-0411 at Figs. 8A-E, Fig. 9, 3:35-37, 12:56-13:14, 11:60-12:2; Tr. [Warren] 1205:12-1206:7; Tr. [Rowe] 1152:4-25.

2. The ID Erred In Finding That Lumidigm Does Not Disclose Measuring Oxygen Saturation.

The asserted ’648 claims each require a “*user-worn* device” that can measure “oxygen” or “oxygen saturation.”⁷ The ID erred by finding these limitations not satisfied based on errors of law and fact when it concluded that Lumidigm does not enable a *wrist*-worn device for measuring oxygen.

First, the ID focused on the wrong issue—whether Lumidigm enables taking an oxygen saturation measurement “*at the wrist*.” ID 115-118. This is irrelevant as *none* of the Poeze claims recites or requires taking a blood oxygen measurement *at the wrist*—nor could they, because the Poeze specification does not disclose or describe such a measurement. In fact, Masimo’s CEO and named inventor Joseph Kiani conceded that Masimo did not possess the “feasibility” of a user-worn device that could take a blood oxygen measurement at the wrist until *years after* the provisional applications were filed (Tr. [Kiani] 147:3-10, 150:3-12 (confirming Masimo “did not have feasibility” to make such a device “until maybe 2016, 2017”)).

⁷ Asserted claims 22 and 28 of the ’502 patent similarly require a “user-worn” device that can measure “oxygen” or “oxygen saturation.” The ID erred in its obviousness analysis of those claims for the same reasons as stated herein.

The ID accordingly erred as a matter of law by requiring Lumidigm to enable a claim limitation that does not exist (a blood oxygen measurement “at the wrist”). While the ID acknowledged that the Federal Circuit in *In re Kumar* has stated that a *prima facie* case of obviousness may be rebutted with a showing that the prior art is not enabling (ID 115), the ID improperly ignores that the relevant standard under *Kumar* is whether “the prior art method would not produce or would not be expected to produce **the claimed subject matter**.” *In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005); *id.* (rebuttal to obviousness “may take the form of evidence that the prior art does not **enable the claimed subject matter**”); *see also Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1471 (Fed. Cir. 1997) (“In order to render **a claimed apparatus** or method obvious, the prior art must enable one skilled in the art to make and use **the apparatus** or method.”) (citing *Beckman Instr., Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989)). Here, the claimed invention is “a **user-worn** device” capable of taking an “oxygen saturation” measurement. In short, if Lumidigm’s wristwatch could take a blood oxygen measurement **anywhere** on the body (it could), it would enable the claimed subject matter.

Second, the ID committed a further legal error by requiring more enabling disclosure from the prior art than the asserted patent itself provides. There is **no** disclosure, anywhere in the Poeze specification, of taking a blood oxygen measurement at the wrist. Instead, as discussed in section IV.A *supra*, **all** the disclosed embodiments are traditional **finger**-clip sensors for measuring **glucose**. JX-001 at 10:2-11:1 (“this disclosure is described primarily in the context of a finger measurement site”); 7:27-30 (“the present disclosure relates to an interface for a noninvasive glucose sensor”); 10:30-39, 10:62-11:2, 12:26-59, 15:21-23, 16:44-51, 30:3-9. The ID accordingly imposed an enablement standard on the prior art that the Poeze patents themselves would not meet, which was legal error. *See, e.g., In re Publicover*, 813 F. App’x at 532 (rejecting

argument that prior art was “too sparse to adequately explain to a skilled artisan” how to implement disputed limitation because the asserted patent was “just as sparse”); *In re Epstein*, 32 F.3d at 1568 (rejecting argument that prior art was not enabling where patent owner “did not provide the type of detail in his specification that he now argues is necessary in prior art references”); *In re Paulsen*, 30 F.3d at 1481 (rejecting argument that prior art was not enabling where “under the enablement standard that AST would have us apply to Yokoyama, the ’456 patent itself would be non-enabling. . . . If detailed disclosure regarding implementation of known electronic and mechanical components necessary to build a computer were essential for an anticipating reference, then the disclosure in the ’456 patent would also fail to satisfy the enablement requirement.”).

As the ID recognized, Lumidigm expressly discloses that its wristwatch can include “‘extended functionality’ including measurements of ‘*oxygenation* and/or hemoglobin levels in the blood.’” ID 114-15, citing RX-0411 at 17:64-18:2, 19:18-28. The ID found that this “extended functionality” is “*clearly applicable to the user-worn wristwatch*” and relied on it in finding that Lumidigm discloses and enables a user-worn device for measuring the “physiological parameter” recited in 502 claim 12. ID 92. However, the ID found that Lumidigm does not enable a wrist-worn device for measuring blood oxygen. *Id.* But under that standard, the asserted claims would themselves be invalid for failure to describe or enable their full scope. Simply put, if Lumidigm’s disclosure is not enabling of a wrist-worn device measuring blood oxygen (one “species” of user-worn devices measuring the same), the asserted claims of the Poeze patents themselves would be equally invalid for failure to describe or enable to full scope—that is, under the ID’s own logic, the claims would fail on written description and enablement grounds.

Third, even if enablement of a measurement at a wrist were required (it is not) and even if the ID could properly require more from Lumidigm’s disclosure than from the Poeze patents’

disclosure (it cannot), the ID still clearly erred in finding that a POSITA would not have understood how to take a blood oxygen measurement, including at the wrist, from Lumidigm's disclosure. Given Lumidigm's express disclosure of a wrist-worn device for taking an oxygen saturation measurement, there is a **presumption** of enablement. *See Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1316 (Fed. Cir. 2008) (“[A]n accused infringer ... enjoys a presumption that the anticipating disclosure also enables the claimed invention.”). Complainants bore the burden of overcoming this presumption with “persuasive evidence.” *See id.* The ID clearly erred in finding they did so. ID 115.

Apple's expert Professor Warren confirmed that oxygen saturation measurements were a “standard reflectance mode sensor application” long before the Poeze patents⁸ and that a POSITA “would not have needed any additional information to make [pulse oximetry functionality] work” in Lumidigm's watch embodiment because this functionality was well understood at the time. Tr. 1216:10-25. Masimo's own expert, Dr. Madisetti, provided **no** testimony to the contrary. Although he characterized Lumidigm's disclosure as “vague and aspirational” (1330:20-1331:11), he provided no opinion on lack of enablement. The expert record thus stands **unrebutted** that a POSITA would have understood how to take a blood oxygen measurement with a wrist-based device. Indeed, for the reasons referenced above, if more disclosure were required to enable a POSITA to take a measurement on the wrist, the Poeze patents would themselves fail the test. *See In re Epstein*, 32 F.3d at 1568 (holding lack of disclosure in asserted patent regarding particular limitations supported finding that a POSITA “would have known how to implement the features” without explicit teachings and that the prior art was thus enabling).

⁸ The Poeze specification similarly confirms that using pulse oximeters to take oxygen saturation measurements was the “standard of care” before the Poeze Patents. JX-001 [’501 patent] 2:15-29.

Significantly, Dr. Warren further confirmed that his own *undergraduate* students were building pulse oximeters and taking oxygen saturation measurements—including *at the wrist*—by 2002, more than six years before the Poeze priority date:

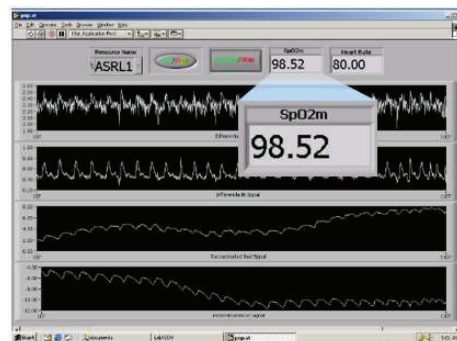
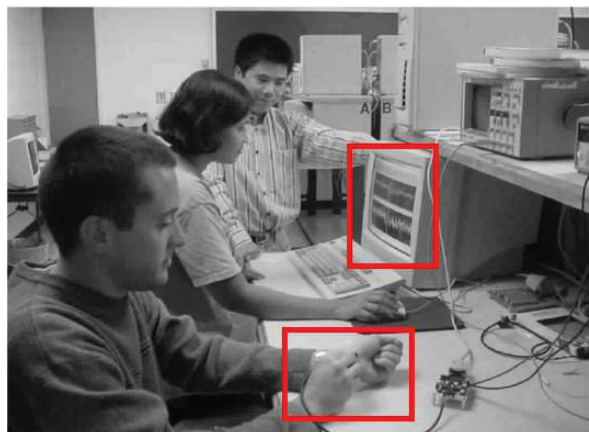


Figure 4. LabVIEW virtual instrument for the pulse oximeter. In addition to heart rate and blood oxygen saturation (%), the interface displays the red and infrared derivative data (top two waveforms) and the red and infrared reconstructed data (bottom two waveforms).

RX-0632 [2002 photograph] (annotated); RX-0508 [2005 paper] (annotated); Tr. [Warren] 1195:24-1196:10, 1216:10-25, 11:96:8-10 (“Q. Is that [a student] on the left taking a measurement from his wrist? A. It is, yes.”). The ID improperly dismissed this evidence because Dr. Warren “provided no testimony regarding the results of those measurements.” (ID 117.) But multiple corroborating documents, all published before the Poeze patents’ priority date, explicitly corroborated Dr. Warren’s testimony that a POSITA would have understood how to take a blood oxygen measurement at the wrist and that his students were doing so. *See, e.g.*, RX-0504.0001 [2005 student poster identifying the “[w]rist” as a “[v]iable and [u]nobtrusive [m]easuring [s]ite[.]” for pulse oximeters); RX-0508.0007 [2005 student article identifying the “wrist” as location for acquiring pulse oximetry signals]; RX-00335.001 at abstract, Fig. 3, 3:11-20, cl. 29 [patent, filed in 1996, describing oximetry probe for measuring “oxygen saturation” at locations including “wrist”].

The ID premised its finding primarily on testimony from Apple engineers concerning the challenges they faced in developing Apple Watch. ID 115-16. None of the cited testimony,

however, suggests measuring blood oxygen at the wrist was impossible at the time of the Poeze patents, or speaks at all to the disclosures of Lumidigm. Instead, as all these witnesses confirmed, while the wrist does differ from other parts of the body, the challenges they faced in developing Apple's blood oxygen feature did not relate to the fundamental elements of pulse oximetry (which the Poeze patents attempt to claim), but instead related to adding that known functionality into the limited space of a small consumer device—while accounting for other considerations such as limited battery power, interference from other features, internal shipping deadlines, and Apple's exacting industrial design standards that prioritized visual appearance. *See* Tr. [Warren] 1217:11-21, 1243:5-16; Tr. [Land] 963:19-964:25, 971:14-972:8; Tr. [Venugopal] 832:20-833:10; Tr. [Mehra] 853:22-854:855:3, 877:23-878:16; Tr. [Block] 902:13-903:2; Tr. [Waydo] 923:24-924:16, 925:23-926:6, 938:21-24; Tr. [Mannheimer] 998:15-999:11; Tr. [Kiani] 114:20-22. It was Apple's need to ensure the feature would work across diverse populations and environments that took time to solve, not the underlying application of pulse oximetry.⁹

Finally, the ID also cited the testimony of one of Lumidigm's inventors that he never personally built a wrist-worn device that calculated blood oxygen. ID 115. But it is textbook law that a patent can enable an invention even when there is no actual product. *See, e.g., In re Antor Media Corp.*, 689 F.3d 1282, 1290 (Fed. Cir. 2012) (“[O]ur precedent hold[s] that the invention in a prior art publication need not have actually been made or performed to satisfy enablement.”).

⁹ For the same reasons, the testimony of the Apple engineers does not support the secondary consideration of skepticism of the claimed invention and the testimony and evidence presented by Dr. Warren weighs against it.

Dated: January 23, 2023

Respectfully Submitted,

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EXHIBIT 9

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

In the Matter of

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

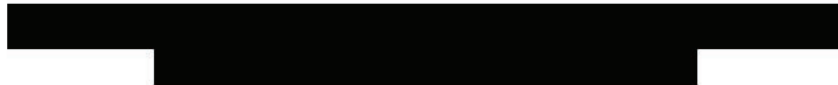
**COMPLAINANTS' PETITION FOR REVIEW OF THE FINAL INITIAL
DETERMINATION ON VIOLATION OF SECTION 337**

Accordingly, the ID's obviousness analysis regarding '501 Patent Element [1E] legally erred by ignoring the entirety of the claimed requirements and should be reversed. If the Commission reverses and upholds the validity of '501 Claim 12, the result would be a Section 337 violation for the '501 Patent.

B. Issue No. 2: Though the ID Correctly Found Nonobviousness of '502 Patent Claim 28, the ID Legally Erred with regard to Element [28G]

If the Commission reviews any part of the ID's obviousness analysis for '502 Patent Claim 28, it should reverse the ID's finding that Lumidigm discloses a "plurality of transmissive windows" as recited by Element [28G]. ID at 131.

Element [28G] recites "a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings." Apple provided no evidence that a POSITA would have been motivated to modify Lumidigm's faceplate into multiple windows. The ID found that "Lumidigm discloses a single window [such as a fiber-optic faceplate]," but made no finding regarding a motivation to modify Lumidigm's single faceplate into multiple windows. *Id.* at 131. Instead, the ID observed that "Warren suggests that 'a person of skill would know that you *could do* an individual faceplate for each of the individual openings as a means to provide light but still optimize the process.'" *Id.* at 131 (quoting Tr. (Warren) 1221:16-1222:25). But as the ID recognizes elsewhere, Warren's testimony "of what [a POSITA] *could theoretically do* is insufficient to clearly and convincingly show that Lumidigm discloses this arrangement, or provide a reason for [a POSITA] to modify Lumidigm to do so." *Id.* at 121; *see, e.g., Adidas AG*, 963 F.3d at 1359 (obviousness inquiry does not ask what a POSITA "could" do, but instead asks what "they *would have been motivated to do*"). Thus, the ID committed legal error by finding that Lumidigm satisfied the requirements of Element [28G] based on Warren's testimony about what a POSITA "could do."



The ID also made no findings on whether a POSITA would have had a reasonable expectation of success in modifying Lumidigm's face plate into multiple windows. ID at 131. Warren identified other references with windows, but Apple provided no evidence that a POSITA *would have modified* Lumidigm's face plate into multiple windows with a reasonable expectation of success. RIB at 84-85; *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 706 (Fed. Cir. 2012) (obviousness finding requires clear and convincing evidence that a POSITA "would have had a reasonable expectation of success" in modifying the prior art). Thus, the lack of any reasonable expectation of success analysis confirms the ID legally erred to the extent it found Lumidigm satisfied Element [28G].

C. Issue No. 3: Though the ID Correctly Found Nonobviousness of the '502 and '648 Patents, the ID Legally Erred and Made Clearly Erroneous Factual Findings in its Analysis of the Protrusion Comprising a Convex Surface Elements of the '502 and '648 Patents ('502 Patent Elements [19C], [28E]; '648 Patent Elements [8D], [20C])

As explained above regarding '501 Patent Element [1C] ("a protrusion comprising a convex surface"), the ID erred in finding a POSITA would have been motivated to modify Lumidigm to add a protrusion comprising a convex surface. *Supra* Section IV.A.3. The ID relies on that same erroneous analysis in its analysis of the "protrusion" elements of the remaining asserted claims of the Poeze Patents. ID at 120 (analysis for '502 Patent Element [19C]), 130 ('502 Patent Element [28E]), 139 ('648 Element Patent [8D]), 141 ('648 Element Patent [20C]). Thus, if the Commission reviews any part of the ID's obviousness analysis for '502 Patent Claims 22 or 28, or '648 Patent Claims 12, 24, or 30, it should reverse any findings regarding the "protrusion" elements of those claims—'502 Patent Elements [19C] and [28E], and '648 Patent Elements [8D] and [20C]—for the reasons discussed above for '501 Patent Element [1C].

IX. CONCLUSION

The Commission should affirm the ID's current finding of a Section 337 violation and find a broader violation for all five asserted patents based on the arguments and evidence set forth in this petition.

Dated: January 23, 2023

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EXHIBIT 10

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**In the Matter of
CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**RESPONDENT APPLE INC.'S RESPONSE TO
COMPLAINANTS' PETITION FOR REVIEW**

head, made from opaque materials, “to implement the optical surface in a convex shape for the reasons that are explicitly disclosed in Lumidigm.” ID 101.⁴

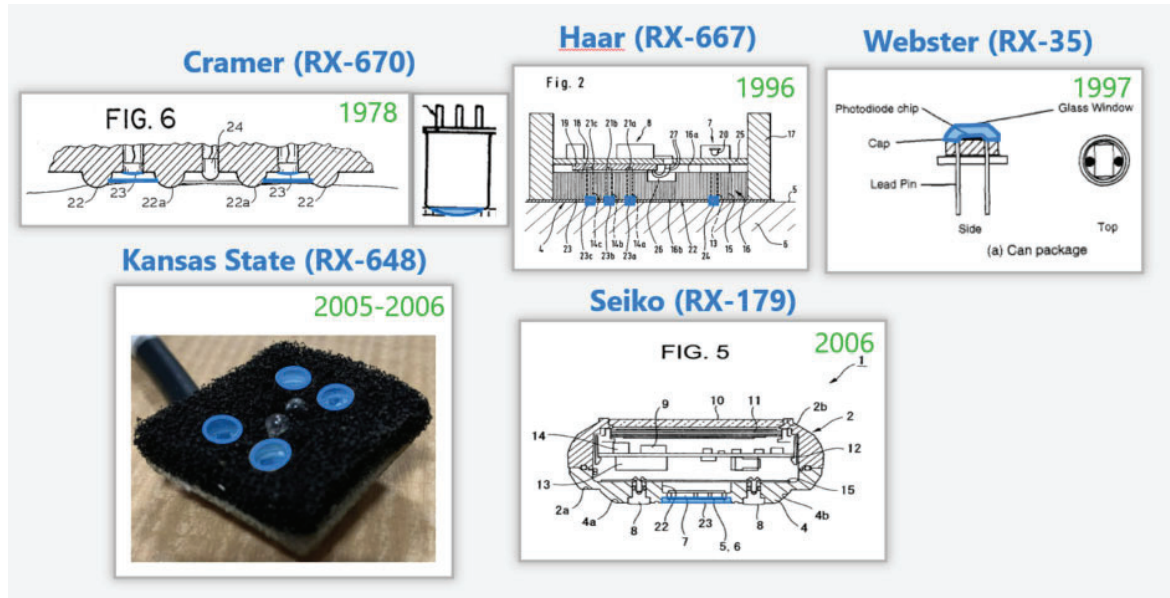
B. Issue No. 2: The ID Applied The Correct Law In Evaluating ’502 Claim 28 Element [28G], And Substantial Evidence Supported Its Finding.

Complainants once again attempt to turn a factual issue into a legal one, claiming that the ID also applied the wrong legal standard in assessing the “transmissive windows” limitation. CPFR 23. Complainants have identified no such legal errors, however. Nor have they identified any clearly erroneous factual findings.

The ALJ correctly found that Lumidigm satisfies the “transmissive windows” limitation based on Lumidigm’s express teachings and Dr. Warren’s testimony on the state of the art. ID 131. As Professor Warren explained in the testimony cited in the ID, the use of transparent windows or other optically transparent materials, within or across openings over photodiodes, was “quite well-known” in the art, both to help transfer light and to protect the photodiodes from dirt

⁴ On January 24 and 30, 2022, the PTAB denied institution of Apple’s IPR petitions on the asserted Poeze patents. Those denials should not impact the issues here, because the petitions raised different grounds of invalidity. To be clear, had the PTAB granted those petitions based on different grounds and different prior art, that would have been yet further indication of the profound invalidity problems that previously led the PTAB to invalidate over 99% of over 300 challenged claims in other patents in the Poeze patent family. But the most recent denials lacked the benefit of the complete prior art record presented in the ITC. As the Commission and Federal Circuit have recognized in other contexts, while the Commission can take judicial notice of IPR proceedings—and Respondent has requested precisely that in its petition for review—the outcome of IPR proceedings are not binding upon the Commission, particularly where the Federal Circuit has not yet considered the issue. *Certain Hybrid Electric Vehicles and Components Thereof*, Inv. No. 337-1042, Notice of Investigation at 1 (Mar. 7, 2017) (Commission instituting investigation over proposed Respondents’ objection that asserted claims had been found unpatentable in IPR proceedings and were on appeal to Federal Circuit); *see also Nobel Biocare Servs. AG v. Intradent USA, Inc.*, 903 F.3d 1365, 1375 (Fed. Cir. 2018), as amended (Sept. 20, 2018) (“We thus conclude that our prior affirmance of the ITC’s judgment on a different factual record ... does not dictate the outcome of this appeal [from an IPR decision].”); *Cisco Sys., Inc. v. Int’l Trade Comm’n*, No. 2017-2289 (Fed. Cir. Sept. 22, 2017) (declining to stay exclusion order pending inter partes review).

or debris. Tr. [Warren] 1193:24-1194:14, 1221:16-1222-9. Professor Warren provided many examples including those below:



Id.; see also RX-0035, RX-0179, RX-0670, RX-0648, RX-0667, RX0670. Consistent with this well-known idea, Lumidigm explains that its sensor can incorporate “an **optical relay** (not shown) between the sensor surface 39 and the skin 40” that “transfers the light . . . from the skin back to the detector(s) while minimizing light loss and spreading.” RX-0411 at 8:19-23. Lumidigm also identifies specific examples of such optical relays, including “**fiber optic face plates**,” “individual optical fibers,” and “fiber bundles,” and further confirms that “other mechanisms” are “known to one of skill in the art.” RX-0411 at 8:23-26.

As Dr. Warren further explained in the testimony cited in the ID, a POSITA would have understood that the fiber optic face plates, individual optical fibers, and fiber bundles referenced in Lumidigm were well known in the art, typically made of glass or plastic cladding, and could be placed within or arranged over the openings to transfer light and to protect the photodiodes. Tr.

[Warren] 1221:16-1222:25. A POSITA would have further understood that the fiber optics face plates referenced in Lumidigm could be implemented as a single faceplate or as individual faceplates over each opening and would have been motivated to implement either alternative. *Id.*

Complainants' contention that Apple provided no evidence that a POSITA would have been motivated to use separate windows over each opening (CPFR 23) is wrong. Dr. Warren confirmed that the use of transmissive windows extending across openings over photodiodes was "well-known" in the art and provided multiple examples. Tr. [Warren] 1221:16-1222:9, 1193:24-1194:14. He further confirmed that a POSITA would have understood that the "fiber optic face plates" *explicitly referenced* in Lumidigm could be implemented as a single face plate or as individual faceplates over each of the openings. *Id.* at 1221:16-1222:9. Contrary to Complainants' argument, this is not a case where the ALJ relied on "speculation" about what a POSITA could "theoretically" do. Instead, Lumidigm identifies and advocates the use of a *specific* structure—a "fiber optic face plate"—that a POSITA would recognize could be implemented in two ways. As the Supreme Court has held and the Federal Circuit has repeatedly confirmed, where a small number of alternatives are known in the art and a POSITA would understand how to implement them, they are obvious. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007) ("[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill."); *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1315 (Fed. Cir. 2008) (claim obvious where it recited one of "two alternative means" for communication, both of which "have long been known and understood by persons of ordinary skill in the art," and the prior art disclosed the other alternative means); *In re Law*, 303 F.2d 951, 953-54 (C.C.P.A. 1962) (confirming that choice between known "design alternatives" would be

obvious to a POSITA); *In re Kuhle*, 526 F.2d 553, 555 (C.C.P.A. 1975) (a “matter of design choice within the skill of the art” is obvious); *In re Magna Elecs., Inc.*, 611 F. App’x 969, 974 (Fed. Cir. 2015) (same); *see also Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020) (claims obvious based on disclosure of single prior art reference combined with knowledge of a POSITA); *Game & Tech. Co. v. Activision Blizzard Inc.*, 926 F.3d 1370, 1381 (Fed. Cir. 2019) (confirming that patent can be obvious based on single prior art reference if it would have been obvious to modify that reference to arrive at claimed invention).

Finally, the caselaw cited by Complainants does not support their arguments. *Adidas AG v. Nike, Inc.*, 963 F.3d 1355 (Fed. Cir. 2020), affirmed a finding that a combination was not obvious based on “[f]undamental differences [in methods] between” two prior art references. *Id.* at 1359. And *OSRAM Sylvania, Inc. v. American Induction Technologies, Inc.*, 701 F.3d 698, 706 (Fed. Cir. 2012), simply found a lack of evidence to support a summary judgment ruling. In this case, in contrast, there is no evidence of “fundamental differences” between two prior art references, and the full trial record provided substantial evidence supporting the finding.

C. Issue No. 3: The ID Applied The Correct Law In Analyzing The Protrusion Comprising A Convex Surface Elements Of The ’502 And ’648 Claims, And Substantial Evidence Supports Its Findings.

For the reasons discussed above (*supra* § III(A)(3)), the ID correctly found Lumidigm rendered Limitation [1C] of the ’501 patent obvious. Complainants have not identified any legal errors in the ID’s analysis. Nor have they identified any clearly erroneous factual findings. Complainants’ similar arguments regarding the ’502 and ’648 claims should be rejected.

sensor products, the ID (at 329) correctly held that Complainants cannot show satisfaction of the economic prong under subparagraph (A) for either the early or the current rainbow sensor products.

VII. CONCLUSION

For the foregoing reasons and those presented in Apple's own Petition for Review, the Commission should take review but confine its analysis to issues pertaining to the only two patent claims found to be violated in the ID, i.e., '648 claims 24 and 30.

Dated: January 31, 2023

Respectfully Submitted,

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EXHIBIT 11

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

In the Matter of

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**COMPLAINANTS' OPPOSITION TO RESPONDENT APPLE INC.'S MOTION TO
STAY EXCLUSION AND CEASE AND DESIST ORDERS PENDING APPEAL AND/OR
IN LIGHT OF THE POTENTIAL GOVERNMENT SHUTDOWN**

[REDACTED]

disclosure. When Apple presented its IPR petitions to the Patent Office, it always combined Lumidigm with other references. And where it made those combinations, the Patent Office rejected Apple’s “proposed amalgamation of prior art teachings” as a “convoluted combination” that was “grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art.” CRRPR (Doc ID 789044), Appx. A at 18-19. The Patent Office held “we cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.” *Id.* at 17 (quoting *Metalcraft*, 848 F.3d at 1367). The Commission correctly observed that its findings and conclusions were consistent with those of the Patent Office. Comm’n Op. at 42, 43.

Moreover, even if substantial evidence did not support the Final ID finding that Lumidigm would not have enabled a POSITA to measure oxygen saturation at the wrist, such error would have been harmless in view of the Commission’s additional findings concerning Lumidigm. When affirming the Final ID’s nonobviousness conclusion, the Commission made detailed findings of fact that provide *independent grounds* supporting its conclusion of nonobviousness for claims 22 and 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent. Indeed, as explained above, the Commission made detailed factual findings that various additional claim elements were not taught by Lumidigm or combinations therewith. Comm’n Op. at 21-44. Thus, Apple’s argument concerning Lumidigm could not possibly undermine the Commission’s non-obviousness conclusion. Accordingly, Apple’s Motion identifies, at most, a harmless factual error, which cannot possibly present an admittedly difficult legal question warranting a stay pending appeal.

IV. APPLE HAS NOT SHOWN THE OTHER FACTORS REQUIRED FOR A STAY ANALYSIS

Even if Apple could identify any admittedly difficult legal question in the Commission’s ruling, which it has not, Apple fails to satisfy any of the other factors in a stay analysis.

A. Apple's Assertions of Irreparable Harm Are Unsupported and Speculative

Apple argues it would “lose goodwill” and “suffer significant damage to its reputation” as a result of this Commission’s remedial orders. Br. at 18. That is pure attorney argument supported by no evidence. Moreover, even if it were true, Apple assumed that risk when it chose to continue to import new models of Apple Watches that infringe Masimo’s patents every year since this investigation began in 2021. Apple cites no Commission decision in which goodwill or reputational harm provided a sufficient basis to delay enforcement of the Commission’s remedies.

The Commission has already rejected Apple’s assertions of harm based on purported supply chain issues, finding that “Apple failed to substantiate its position that manufacturers of suitable alternative products lack the manufacturing capability to ramp up production to meet any demand.” Comm’n Op. at 110.

Apple also suggests that a stay could minimize the public statements regarding Apple’s copying of Masimo’s technology and Apple’s pattern of “efficient infringement.” Br. at 19-20. But Apple’s pursuit of Masimo’s technology and Apple’s hiring away of Masimo employees is well documented in numerous public filings outside of this proceeding. CRPNR (Doc. ID 798353) at Ex. 54; *see also* Doc. ID 799194 (public version) at Ex. 54 (public testimony); Appendix A-C (public filings in California). So is Apple’s routine practice of efficient infringement. *See* Alliance for U.S. Startups Stmt. (Doc. ID 791674) (discussing Apple’s practices). Nothing in this investigation can erase Apple’s conduct from public scrutiny.

B. Masimo Is Entitled to Prompt Enforcement of the Remedial Orders

Apple suggests that the parties’ pending litigation in Delaware and the current sales revenue for Masimo’s W1 Watch means that Masimo will not suffer significant harm. Again, Apple cites no Commission decision granting a stay in such circumstances.

[REDACTED]

specifically requested the parties in May 2023 to “explain how easily the infringing features of the Apple Watches could be removed,” “whether Apple is working on any redesigns with respect to the infringing features and how long implementations of any redesigns would take.” NR (Doc ID 796515) at 5. Apple was not forthcoming, and instead informed the Commission in June 2023 it was merely “exploring” a design change that “would require significant human and other resources to execute.” RRNR (Doc. ID 797870) at 72-73. Just four months later, Apple now admits that it has initiated a proceeding with the EOE Branch to adjudicate redesigned watches, is seeking expedited treatment in that proceeding, and is concerned that a government shutdown will prevent prompt adjudication. Br. at 4 n.1, 5, 27. But that is a problem of Apple’s own making. Apple either concealed that redesign throughout the ITC proceedings, or assumed that it would prevail before the Commission. Apple assumed the risk of exclusion, and cannot complain now that it might lack the time to have its proposed redesign promptly adjudicated by the EOE Branch. The Commission should reject Apple’s attempt to avoid the consequences of its infringement, of its decision not to disclose its redesign to the ITC, and of the Commission’s orders.

VI. CONCLUSION

The Commission should deny Apple’s second attempt to stay enforcement of its remedial orders. There is no admittedly difficult legal question in the Commission’s ruling, and Apple’s distortion of the record does not show otherwise.

Respectfully submitted,

Dated: November 9, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of January, 2024, I caused the Confidential Reply in Support of Appellant Apple Inc.'s Emergency Motion to Stay Enforcement of ITC's Orders Pending Review to be emailed to counsel for Appellee International Trade Commission and Intervenors Masimo Corporation; Cercacor Laboratories, Inc. at the following email address listed on the Court's docket:

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